# 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

ΑE Adverse event

**AESI** Adverse event(s) of special interest

Anti-nucleocapsid Anti-N

aTIV Adjuvanted trivalent influenza vaccine

BMI Body mass index

**CDC** Centers for Disease Control and Prevention

CI Confidence interval

CMI

Cell-mediated immunity
Federal Commission for Protection against Sanitary Risks **COFEPRIS** 

COVID-19 Coronavirus disease 2019

DP Drug product DS Drug substance

Data and Safety Monitoring Board **DSMB** 

Events per 100 person-years e/100 PY

**EBSI Emergent BioSolutions** 

**eCRF** Electronic case report form

European Medicines Agency **EMA** 

Independent Endpoint Review Committee **ERC** 

Emergency use authorization **EUA** 

FujiFilm Diosynth Biotechnologies **FDBU** 

Good Clinical Practice **GCP** 

**GLP** Good Laboratory Practice

hACE2 Human angiotensin-converting enzyme 2

Hemagglutination inhibition

Heptad repeat 1

Human immunodeficiency virus

Lower bound confidence interval **LBCI** 

**IgG** Immunoglobulin G

Intramuscular IM IR Incidence rate

Dogo 6

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 adjovant

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

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

The Type 1 T helper
The Type 2 T helper
UK United Kingdom

ULOQ Upper limit of quantitation

US United States

SARS-CoV-2 rS wi	th Matrix-M Adjuvant
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## 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 > 60°C), and specifically bind to the human angiotensin-converting enzyme 2 (hACE2) receptor, the receptor used by SARS-GoV-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 Quilfaja 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 phosphotopids 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.

### **COVID-19 Background** 2.5.1.2

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 appinals, 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 [Kimpra 2021].

### Clinical Development Program 2.5.1.3

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-2-75 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) S) With or Without Matrix-M<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> Adjuvant in Adult

Participants ≥ 18 Years with a Pediatric Expansion in Adolescents

(12 to < 18 Years)

Enrollment and primary vaccination (ie, Day's 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  $\geq$  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.

- Part 1 blinded, placel healthy adults age	omized, observer- bo-controlled in ≥ 18 to ≤ 59 years of	Safety Immunogenicity	Dose 1 (Day 0)/Dose 2 (Day 21) <sup>2</sup> A: Placebo/ Placebo B: 25 µg+0 µg/ 25 µg+0 µg C: 5 µg+50 µg/ 5 µg+50 µg D: 25 µg+50 µg/ 25 µg+50 µg E: 25 µg + 50 µg/ Placebo  IM injection on Days Q and 24 (+ 7 days); anticen and adjuvant were administered as a bedside mixture	Total: 131 (131) A: 25 (23) B: 25 (25) C: 28 (29) D: 28 (28) E: 25 (26)	Ongoing Carbollment and treatment complete); Day 35 and Day 189 interim analyses complete	Protocol (Version 8.0 – dated 17 Dec 2020)  Statistical analysis plan (Version 2.1 – dated 17 Dec 2020)  Interim study
		marke	ting authorise			report through Day 189 (Version 1.0 – dated 25 Feb 2021)  Publication
at cannot be	sused to suppor	it any marke	E: 25 μg + 50 μg/ Placebo  IM injection on Days (and 24) (+ 7 days); antigen and adjuvant were administered as a bedside mixture			

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 Safety	Dose 1 (Day 0)/Dose 2 (Day 21) <sup>2</sup> A: Placebo/ Placebo B: 5 μg+50 μg/ 5 μg+50 μg C: 5 μg+50 μg/ Placebo D: 25 μg+50 μg/ Placebo B: 25 μg+50 μg/ Placebo Booster Dose 3 (Day 189) A: Placebo B1: Placebo B2: 5 μg+50 μg C1: Placebo E: 5 μg+50 μg D: Placebo E: 5 μg+50 μg C1: 5 μg+50 μg C2: Placebo	Total: 750-1,500 (1,283)  A: 150-300 (255) B: 150-300 (258) C: 150-300 (259) D: 150-300 (255) E: 150-300 (255)	Ongoing Chrollment 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)  Statistical analysis plan (Version 2.0 – dated 02 Dec 2020)  Interim study report through Day 35 (Version 1.0 – dated 10 Mar 2021)  Publications ([Formica 2021])

Clinical Study Number (Country)	Study Design	Primary Endpoints	Dosage, Duration and Dosage Regimen	Planned (Treated) Number of Subjects	Study Status <sup>1</sup>	Cross-References
2019nCoV-501 (South Africa)	Phase 2a/2b, randomized, observerblinded, 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.  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 Immunogenicity Safety	Initial Set of Vaccinations  5 µg SARS-CoV-2 rS +  50 µg Matrix-M adjuvant or Placebo  Crossover Set of Vaccinations  5 µg SARS-CoV-2 rS +  50 µg Matrix-M adjuvant or Placebo  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)  SARS-CoV 2 rS: 1,480-2,082 (2,211 [2,089 HIV-negative/ 122 HIV-positive])  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)  Statistical analysis plan (Version 2.0 dated 28 Apr 2021)  Interim study report (Version 1.0 – dated 19 May 2021)  Publications ([Shinde 2021])
is document	of the Crossover Vaccination Period.4					

**Clinical Study Primary** Dosage, Duration and Planned (Treated) Study Status<sup>1</sup> Number **Study Design** Cross-References **Endpoints Dosage Regimen Number of Subjects** (Country) Ongoing 2019nCoV-302 A Phase 3, multicenter, randomized, Efficacy Initial Set of Vaccinations Total: 15.000 Protocol (Version Carollment and 4.0 – dated 25 Feb observer-blinded, placebo-controlled (15,139)(UK) Immunogenicity  $5 \mu g SARS-CoV-2 rS +$ initial study evaluating the efficacy, safety, 2021) Safety 50 μg Matrix-M adjuvant or and immunogenicity of SARS-CoVvaccinations Placebo 2 rS with Matrix-M adjuvant in adult complete and Statistical analysis Influenza vaccine (in a substudy of participants  $\geq 18$  to  $\leq 84$  years. crossover Placebo: plan (Version 4.0 – approximately 400 participants) vaccinations Crossover Set of Vaccinations Dication dated 05 Mar 7,500 (7,570) complete); Includes an influenza vaccine 2021) primary efficacy co-administration substudy and a analysis complete blinded crossover vaccination period Interim study initiated after achieving the primary report for Main efficacy endpoint. Study (Version 1.0 - dated 06 May IM injection on Days 0 (with influenza This document cannot be used to support any market a In the Crossover Vaccination Period. 2021) vaccine) and 21 (+ 7 days) of Initial and Crossover Vaccination Periods; Interim study antigen and adjuvant were report for Flu administered as a co-formulation Substudy (Version 1.0 – dated 02 Aug 2021) Publications ([Heath 2021])

the Sixts 60 v 215 vuccine omitted 20 veropinent i rogram							
Clinical Study Number (Country)	Study Design	Primary Endpoints	Dosage, Duration and Dosage Regimen	Planned (Treated) Number of Subjects	Study Status <sup>1</sup>	Cross-References	
2019nCoV-301 (US and Mexico)	A Phase 3, randomized, observerblinded, 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).  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). In the Crossover Vaccination Period, participants will receive the alternate trial vaccine or placebo than received in the Initial Set of Vaccinations.   A plication (EUA). So In the Crossover Vaccination Period, participants will receive the alternate trial vaccine or placebo than received in the Initial Set of Vaccinations.	<sub>r any marke</sub>	Initial Set of Vaccinations 5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant or Placebo  Crossover Set of Vaccinations 5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant or Placebo  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: Total: 30,000 (29,582)  SARS-CoV-2 rS: 20,000 (19,729) Placebo: 10,000 (9,853)  Pediatric Expansion: <sup>3</sup> Total: 3,000 (2,248)	Adul Main Study: Ongoing (enrollment, initial and crossover vaccinations complete); primary efficacy analysis complete  Pediatric Expansion: Ongoing (enrollment and initial vaccination complete, crossover vaccinations initiated)	Protocol (Version 9.0 – dated 14 May 2021)  Statistical analysis plan (Version 5.0 – dated 31 May 2021)  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).

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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 process accordance with the emerging global guidelines for COVID-10 including, but not limited to, those issue 3.1

Medicines and II. 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 2019aCoV-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 202 19,104 participants received NVX-CoV2373 in Clinical Study 2019nCoV 202 (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

### 2.5.2 OVERVIEW OF BIOPHARMACEUTICS

### 2.5.2.1 **Product Overview**

Novavax, Inc.

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  $\geq 18$  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

1 abit 2.5-2.	2011111017 01 81		- Coca in Cinn	cui iiiuis			E there
DP Lot	Phase Study No (Country) <sup>1</sup>	DP Manufacturer /Address	DP DOM	DP Presentation	DS Lot	DS DOM	DS Manufacturer Address
Initial Vaccina	ation (Days 0 and 21	[+ 7 days])					OL
2868-101	Phase 1 2019nCoV-101 Part 1	Emergent BioSolutions Baltimore, MD, US	29 Apr 2020	70 μg/mL antigen (bedside mixing with Matrix-M) 0.7 mL single-dose via <sup>6</sup>	M00000008	17 Apr 2020 ions	Emergent Manufacturing Operations, LLC Baltimore, MD, US
2868-102	Phase 1 2019nCoV-101 Part 1	Emergent BioSolutions Baltimore, MD, US	12 May 2020	70 μg/mL antigen (bedside mixing with Matrix-M) <sup>6</sup>	M00000001gno	28 Apr 2020	Emergent Manufacturing Operations, LLC Baltimore, MD, US
2871-101	Phase 2 2019nCoV-101 Part 2	Emergent BioSolutions Baltimore, MD, US	17 Jul 2020	50 μg/mL antigen 100 μg/mL Matrix-M 0.7 mL single-dose vial	Q21001673	20 Jun 2020	Emergent Manufacturing Operations, LLC Baltimore, MD, US
2870-101	Phase 2 2019nCoV-101 Part 2 Phase 2 2019nCoV-501 Phase 3	Emergent BioSolutions Baltimore, MD, US	20 Jul 2020 any marketi	10 μg/mL antigen w/ 000 μg/mL Matrix-M 0.7 mL single-dose vial	21001673	20 Jun 2020	Emergent Manufacturing Operations, LLC Baltimore, MD, US
2870-102	2019nCoV-302  Phase 3 2019nCoV-302  Phase 2 2019nCoV-501	Emergent BioSolutions Baltimore, MD, US	17 Aug 2020	10 μg/mL antigen w/ 100 μg/mL Matrix-M 0.7 mL single-dose vial	21001692	04 Jul 2020	Emergent Manufacturing Operations, LLC Baltimore, MD, US
Par 28003	Phase 3 2019nCoV-301	Par Sterile Products, LLC 870 Parkdale Road Rochester, MI 48307 US	12 Nov 2020	10 μg/mL antigen w/ 100 μg/mL Matrix-M 6.0 mL multi-dose vial	GR1350007	05 Nov 2020	FujiFilm Diosynth Biotechnologies, Research Triangle Park, NC, US (FDBU)

	Phase Study No	DP Manufacturer					DS Manufacturer	
DP Lot	(Country) <sup>1</sup>	/Address	DP DOM	DP Presentation	DS Lot	DS DOM	Address	
Booster or Blinded Crossover Vaccination (Data not available for initial application)         Par 28003       Phase 2       Par Sterile       12 Nov 2020       10 μg/mL antigen + 100 μg/mL Matrix-M       GR1350007       05 Nov 2020 in FujiFilm Diosynth Biotechnologies, Research Triangle Park, NC, US (FDBU)         Part 2²       870 Parkdale Road Rochester, MI Phase 2 2019nCoV-501³       48307 US       6.0 mL multi-dose vial       NC, US (FDBU)								
Par 28003	Phase 2	Par Sterile	12 Nov 2020	10 μg/mL antigen +	GR1350007	05 Nov 2020	FujiFilm Diosynth	
	2019nCoV-101	Products, LLC		100 μg/mL Matrix-M		rensi	Biotechnologies,	
	Part 2 <sup>2</sup>	870 Parkdale Road		6.0 mL multi-dose vial		exce	Research Triangle Park,	
		Rochester, MI			. 7	M	NC, US (FDBU)	
	Phase 2	48307 US			and.			
	2019nCoV-501 <sup>3</sup>				ion o.			
Par 28004	Phase 3	Par Sterile	15 Dec 2020	10 μg/mL antigen w/	GR2350009	24 Nov 2020	FujiFilm Diosynth	
	2019nCoV-3014	Products, LLC		100 μg/mL Matrix M	b//e		Biotechnologies,	
		870 Parkdale Road		6.0 mL MDV			Research Triangle Park,	
	Phase 3	Rochester, MI		ema satio			NC, US (FDBU)	
	2019nCoV-302 <sup>5</sup>	48307 US		10 µg/mL antigen w/ 200 100 µg/mL Matrix M 6.0 mL MDX emorisation				
	Phase 2		.*\`	ng ac				
	2019nCoV-501 <sup>3</sup>		. Kec.					

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

- 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
- Evaluated in the booster dose at Day 189 in Clinical Study 2019nCoV-101 (Part 2).
- are duale blinded crossated in the Adult Main S.
  Evaluated in the blinded crossov
  6. Matrix-M was from Lot M1-108. Evaluated in the blinded crossover portion of Clinical Study 2019nCoV-501.
  - Evaluated in the Adult Main Study blinded crossover and Pediatric Expansion in Clinical Study 2019nCoV-301.
  - Evaluated in the blinded crossover portion of Clinical Study 2019nCoV-302.

## 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, micropeutralization, 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

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

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

Table 2.5-5:	Bioanalytical Assay Site and Status by Clinical Study [Report]									
Assay	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] <sup>5</sup>	Roche Elecsys® PPD Central Lab (Zaventem, BE) Validated [Anti-SARS-CoV- 2 Assay ©sed 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					
Anti-S Protein Binding IgG ELISA	Novavax Clinica (Gaithersburg Qualit [QAG_0	mied (MD, US)	Novavax Clinical	Novavax Clinical Immunology (Gaithersburg, Maryland, US) Validated [QAG_04556;	Clinical Study 2019nCoV-301 Data not available for interim report <sup>2</sup>					
		Secondary/Exp	QAG_05168] loratory Endpoints <sup>1</sup>	QAG_05168]						
Wild-type Neutralization	University of Maryland School of Medicine (Baltimore, Maryland, US) Fit-for purpose [SOP SARS-CoV 2 Microneutralization]  University of 360biolabs (Meltourne, AU) Qualified [360bl-QR_NOVA-04_MN_v01]		360bi (Melbou Valid [360bl-VR_NOV	Data not available for interim report <sup>3</sup>						
hACE2 Receptor Binding Inhibition ELISA	Assayo  Novavax Clinical Immunology (Gaithersburg, Maryland, US) Validated [QAG_04394; QAG_05890; CL_5.3.1.4_002761]		Data not available for interim report <sup>4</sup>	Data not available for interim report <sup>4</sup>	Data not available for interim report <sup>4</sup>					
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

	Bioanalytical Assay Site and Status by Clinical Study [Report]										
Assay	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) SOR report not available; not validated	University of Washington (Seattle, Washington, US) [VIRO_1800- 3100] SOP only; not validated						

....ated immunity; ELISA = enzyme-linked
....aCE2 = human angiotensin-converting enzyme 2
....aulin G; PCR = polymerase chain reaction; S = spike;
....aut statusfor each assay varies by study.
....aut statusfor each assay varies by study.
....autzation Testing in Clinical Study 2019nCoV-301 will be performed with QAG\_04556.
....autzation Testing in Clinical Study 2019nCoV-301 will be performed with 360bl-VR\_NOVA....aCE2 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® errology 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.

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### 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  $\geq$  18 to  $\leq$  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  $\geq 65$  years of age and participants < 65 years of age with co-morbidities (ie, obesity [body mass index (BMI) > 30 kg/m²], 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), an 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.

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

Efficacy	Clinical Study 2019nCoV-501	Clinical Study 2019nCoV-302	Clinical Study 2019nCoV 301
Objective	To evaluate the efficacy of NVX-CoV2373	To demonstrate the efficacy of NVX-CoV2373 in	To evaluate the efficacy of a two-dose
	compared to placebo on the occurrence of	the prevention of virologically confirmed (by	regimen of NVX-CoV2373 compared to
	symptomatic mild, moderate, or severe	PCR to SARS-CoV-2), symptomatic COVID-	placebo against PCR-confirmed
	confirmed COVID-19 as demonstrated by	19, when given as a two-dose vaccination	symptomatic COVID-19 illness diagnose
	qualitative PCR in serologically naïve (to	regimen, as compared to placebo, in serologically	$\geq$ 7 days after completion of the second
	SARS-CoV-2) healthy HIV-negative and	negative (to SARS-CoV-2) adults.	njection in the initial set of vaccinations of
	medically stable HIV-positive adult participants	ad a	adult participants $\geq$ 18 years of age.
	(analyzed as an overall population; initial	an gi,	
	vaccination period).	negative (to SARS-CoV-2) adults.	
Endpoint	(+) PCR-confirmed SARS-CoV-2 illness with	First occurrence of virologically confirmed (by	First episode of <b>PCR-positive mild</b> ,
	symptomatic mild, moderate, or severe	PCR to SARS-CoV-2), symptomatic mild,	moderate, or severe COVID-19.
	COVID-19 in serologically naïve (to SARS-CoV-	moderate, or severe COVID-19 with onset from	
	2) healthy HIV-negative and medically stable	at least 7 days after second study vaccination	
	HIV-positive adult participants, analyzed overall,	(eg, Day 28) in the initial set of vaccinations in	
	with an LBCI of $> 0$ , from 7 days after the second	serologically negative (to SARS-CoV-2) adult	
	vaccine dose (eg, Day 28) until the endpoint-	participants at baseline until the endpoint-driven	
	driven efficacy analysis is triggered by the	efficacy analysis is triggered by the occurrence of	
	occurrence of a prespecified number of blinded	a prespecified number of blinded endpoints.	
	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.  +) = positive; COVID-19 = coronavirus disease 2019; HIV = 2373 = 5 µg SARS-CoV2 rS with 50 µg Matrix-M adjuvant; -2 rS = severe acute respiratory syndrome coronavirus 2 reco		
	prespecified time points during the initial		
	vaccination period.		

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 eximpter 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<sub>7</sub>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.

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

		•					op.			
Participant Population/		NVX-CoV2373		Placebo		VE (95% CI) <sup>2</sup>	Interim Report			
SARS-CoV-2 Strain/Variant	Cases	<b>n/N</b> (%) <sup>1</sup>	(95% CI)	<b>n/N</b> (%) <sup>1</sup>	(95% CI)	VE (95% CI)	Cross-Reference			
Primary efficacy endpoint (Official Event-Driven vaccination (eg, Day 28) in participants who were	• .					. 🔻	fter second			
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) <sup>3,4</sup>	Table 17			
Post-hoc analyses of the primary efficacy endpoin	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) <sup>4</sup>	Table 18			
HIV-negative: B.1.351 (Beta) variant	33	11/1281 (0.86)	0.4, 1.5	22/1255 (1.75)	and, 2.6	51.0% (-0.6, 76.1)4	Table 19			
Primary efficacy endpoint (Complete Analysis) for (eg, Day 28) in participants who were seronegative							vaccination			
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) <sup>3,4</sup>	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) <sup>4</sup>	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) <sup>4</sup>	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.

- Percentage of participants with COVID-19 calculated as  $n/N \times 100$ .
- 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.
  - Met primary efficacy endpoint criterion for success with a LBCI > 0%.
  - 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

<b>Table 2.5-6:</b>	Vaccine Efficacies for the Primary	and Kev Secondary	Efficacy Endpoints in	Clinical Study 2019nCoV-302
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		NVX-CoV2373		Pl	acebo		thereo
Participant Population SARS-CoV-2 Strain/Variant	No. of Cases	<b>n/N</b> (%) <sup>1</sup>	Mean Disease Incidence Rate <sup>2</sup> (95% CI)	<b>n/N</b> (%) <sup>1</sup>	Mean Disease Incidence Rate <sup>2</sup> (95% CI)	VE (95% CI)	Interim Report Cross-Reference
Primary efficacy endpoint (Interim Ana						7 days after second va	ccination
(eg, Day 28) in participants who were se	ronegativ	e to SARS-CoV-		FF 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) <sup>3,4</sup>	Table 16
Post-hoc analyses of the primary efficac			sis based on PP-EI		Yns,		
All: B.1.1.7 (Alpha) variant <sup>5</sup>	32	4/7008 (< 0.1)		28/7022 (0.4)	:00 300 0,	$85.7\% (59.2, 95.0)^3$	Table 17
All: Non-B.1.1.7 (Alpha) variant <sup>6</sup>	24	1/7008 (< 0.1)		23/7022 (0.3)	· · · · · · · · · · · · · · · · · · ·	$95.6\% (67.7, 99.4)^3$	Table 17
Primary efficacy endpoint (Final Analys						days after second vacci	nation
(eg, Day 28) in participants who were se	ronegativ	e to SARS-CoV-	2 at baseline (PP-E	FF Analysis Set	<u> </u>		
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) <sup>3,4</sup>	Table 18
Post-hoc analysis of the primary efficacy vaccination (eg, Day 28) in participants			) for PCR-confirm	ea miia, modera		D-19 with onset from 7	days after second
All: B.1.1.7 (Alpha) variant <sup>5</sup>	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) <sup>3</sup>	Table 19
All: Non-B.1.1.7 (Alpha) variant <sup>6</sup>	29	1/7020 (< 00)	0.43 (0.05, 3.79)	28/7019 (0.4)	12.15 (4.23, 34.92)	96.4% (73.8, 99.5) <sup>3</sup>	Table 19
Subgroup analyses of the primary effica							7 days after
second vaccination (eg, Day 28) in partic	cipants w	ho were seronega	tive to SARS-CoV	-2 at baseline (P	P-EFF Analysis Set	<b>:</b> )	
Participants 18 to 64 years of age	to 8014	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) <sup>3</sup>	Table 20
Participants 65 to 84 years of age	10	$1(0.10)^3$		$9(0.90)^3$		88.9% (20.2, 99.7) <sup>5</sup>	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) <sup>3</sup>	Table 20
Participants of non-White race <sup>7</sup>	8	2 (0.25)8		6 (0.75)8		66.3% (-88.4, 96.7) <sup>8</sup>	Table 20
Participants of non-White race <sup>9</sup>	10	2 (0.20)8		8 (0.80)8		75.7% (-21.6, 97.5) <sup>8</sup>	Table 20
Participants with co-morbidities <sup>10</sup>	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) <sup>3</sup>	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) <sup>3</sup>	Table 20

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

		NVX-	CoV2373	Pl	acebo		the!		
Participant Population	No. of		Mean Disease		Mean Disease	VE (050/ CI)	Interim Report		
SARS-CoV-2 Strain/Variant	Cases	<b>n/N</b> (%) <sup>1</sup>	Incidence Rate <sup>2</sup>	<b>n/N</b> (%) <sup>1</sup>	Incidence Rate <sup>2</sup>	VE (95% CI)	Cross-Reference		
			(95% CI)		(95% CI)	18	110		
Key secondary efficacy endpoint (Final A	Analysis)	for PCR-confirm	ned moderate or se	vere COVID-19	with onset from 7	days after second vacc	ination		
(eg, Day 28) in participants who were sen	ronegativ	e to SARS-CoV-	2 at baseline (PP-E	FF Analysis Set	)	=iOU2			
All: Any strain/variant	77	9/7020 (0.1)	5.43	68/7019 (1.0)	41.38	86.9% (73.7, 93.5) <sup>3</sup>	Table 24		
All. Ally strain/variant	7.7	9/ /020 (0.1)	(2.54, 11.63)	06/7019 (1.0)	(26.88, 63.72)	00.9% (73.7, 93.3)	Table 24		
Post-hoc analysis of the key efficacy end	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 ba	seline (PP-EFF	Analysis Set				
All: B.1.1.7 (Alpha) variant <sup>5</sup>	50	7/7020 (< 0.1)	4.48	43/7019 (0.6)	27.66	83.8% (64.0, 92.7) <sup>3</sup>	Table 25		
All. B.1.1.7 (Alpha) variant	30	7/7020 (< 0.1)	(1.97, 10.16)	43/7019 (0.0)	(16.84, 45.44)	03.070 (04.0, 92.1)	Table 25		
All: Non-B.1.1.7 (Alpha) variant <sup>6</sup>	20	$1(0.05)^8$		.19 (0.95)		94.8% (67.1, 99.9)8	Table 25		
<b>Exploratory efficacy endpoint (Final An</b>	alysis) for	r PCR-confirme	d mild, moderate,ø	r severe COVII	0-19 with onset from	n 7 days after second v	accination		
(eg, Day 28) in participants who were sen	ronegativ	e to SARS-CoV-	2 at baseline (PP-E	FF Analysis Set	) in the Seasonal In	fluenza Vaccine Subst	udy		
All participants: B.1.1.7 (Alpha) variant <sup>5</sup>	10	2 (1 0)	70.37	8 (4.1)	279.58	74.8% (-19.7, 94.7) <sup>3</sup>	Table 5 <sup>11</sup>		
An participants. B.1.1.7 (Alpha) variant	10	2 (1.0)	(9.46, 523.51)	0 (4.1)	(109.89, 711.26)	74.070 (-19.7, 94.7)	1 4016 3		
Participants 18 to 64 years of age:	9	1 (0.6)	29.74	9 (4 4)	238.01	87.5% (-0.2, 98.4) <sup>3</sup>	Table 6 <sup>11</sup>		
B.1.1.7 (Alpha) variant <sup>5</sup>	9	1 (0.0)	(4.19, 211.21)	8 (4.4)	(118.25, 479.05)	07.3% (-0.2, 90.4)	1 aute 0		

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  $n/N \times 100$ .
- 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  $VE = 100 \times (1 \text{relative risk})$  (Zov. 2004).
- 4. Met primary efficacy endpoin criterion for success with a LBCI > 30%.
- 5. Based on genomic sequencing for B.1.1.7 (Alpha) variant.
- 6. No additional generalic 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.
  - 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<sup>2</sup>.
- 11. From the 2019nCoV-302 Interim Report Flu Substudy.

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

		NVX-0	CoV2373	Pl	acebo		Interim
Participant Population/ SARS-CoV-2 Strain/Variant	No. of Cases	n/N (%) <sup>1</sup>	Mean Disease Incidence Rate <sup>2</sup> (95% CI)	n/N (%) <sup>1</sup>	Mean Disease Incidence Rate <sup>2</sup> (95% CI)	VE (95% CI)	Report Cross- Reference
Primary efficacy endpoint (Final Analys						ays after second vaccination	1
eg, Day 28) in participants who were se	ronegativ	e to SARS-CoV-2	at baseline (PP-EF	F Analysis Set)		2510.	•
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) <sup>3,4</sup>	Table 13
Subgroup analyses of the primary effica- econd vaccination (eg, Day 28) in partic		` •	,	,	* 10	v	s after
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) <sup>3</sup>	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) <sup>3</sup>	Table 14
Female participants	49	9/8262 (0.1)	(3 33-12 30)	40/4009 (1.0)	63.89 (46.85, 87.12)	89.99% (79.36, 95.14) <sup>3</sup>	Table 14
White participants	60	12/13140 (0.1)	(3.10, 9.60)	48/6184 (0.8)	51.31 (38.66, 68.08)	89.37% (79.99, 94.35) <sup>3</sup>	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) <sup>3</sup>	Table 14
Black or African American participants	7 SUP	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) <sup>5</sup>	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) <sup>3</sup>	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) <sup>3</sup>	Table 14
US participants Call	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) <sup>3</sup>	Table 14
Participants with co-morbidities <sup>6</sup>	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) <sup>3</sup>	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) <sup>3</sup>	Table 14

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

		NVX-CoV2373		Placebo			Interim		
Participant Population/ SARS-CoV-2 Strain/Variant	No. of Cases	<b>n/N</b> (%) <sup>1</sup>	Mean Disease Incidence Rate <sup>2</sup> (95% CI)	<b>n/N</b> (%) <sup>1</sup>	Mean Disease Incidence Rate <sup>2</sup> (95% CI)	VE (95% CI)	Report Cross- Reference		
High-risk participants <sup>7</sup>	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) <sup>3</sup>	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) <sup>5</sup>	Table 15		
Kay secondary afficacy andpoint (Final	Analysis)	for PCR-confirm	ed mild moderate	or covered COV	UNITO due to a SAR	S-CoV-2 variant considered	26.0		

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 secongative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)

All participants	44	6/17312 (< 0.1)	1.31 (0.42,406) 38/8140 (0.5)	19.26 (9.62, 38.56)	93.18% (83.87, 97.12) <sup>3</sup>	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 = 5.46 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  $nN \times 100$ .
- Mean disease incidence rate per year in 1000 people.
- 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  $VE = 100 \times (1 - \text{relative risk})$  (Zou 2004).
- 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/m²), chronic kidney disease, chronic lung disease, cardiovascular disease, diabetes mellitus type 2.
- .. auults were de aensely populated circun. populated circumstances. 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

## 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  $\mu g$  SARS-CoV-2 rS with 50  $\mu g$  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  $\geq$  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<sup>+</sup> 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 §G, 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 & G and neutralizing antibody) was assessed on Days 0, 21, and 35.
- In the 2019nCoV-302 Interim Report, immunogenicity for the man 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®, Segirus; also referred to as aTIV) was given to those  $\geq 65$  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.

Clinical Study	Key Immunogenicity Results	Interim Report Cross-Reference
2019nCoV-101 (Part 1)	<ul> <li>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 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):</li></ul>	Section 4.2

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<b>Clinical Study</b>	Key Immunogenicity Results	Interim Report Cross-Reference
2019nCoV-101 (Part 2)	<ul> <li>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):         <ul> <li>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).</li> <li>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).</li> <li>Anti-S protein IgG GMTs for the 5-μg and 25-μg doses at Day 35.0% 100.0%, and 0.0%, respectively (Table 11).</li> <li>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):</li></ul></li></ul>	Section 4.2

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

1 able 2.5-6: 1	key minimunogementy Results Across the SARS-Cov-218 Chinical Development Frogram	ve.
Clinical Study	Key Immunogenicity Results	Interim Report Cross-Reference
2019nCoV-501	<ul> <li>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 endopoint). For participants who were seronegative at baseline, immune responses were approximately 2-fold greater for HIV-positive participants than they were for HIV-positive participants but were comparable when participants in fises 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.</li> <li>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's serostatus (45,103,8 vs 125,0 EU/mL and 99.4% vs 3.6%, respectively), and seropositive at baseline (100,534.1 vs 1,738.3 EU/mL and 90.0% vs 10.0%, respectively) (Table 28).</li> <li>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 90.0% 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).</li> <li>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 97.1% vs 7.9%, respectively) (Table 30).</li> <li>Neutralizing antibody GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in</li></ul>	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)	<ul> <li>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):         <ul> <li>Anti-S protein IgG GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in baseline serongeanive 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).</li> <li>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).</li> <li>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).</li> </ul> </li> <li>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):         <ul> <li>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 (1,241.2 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%,</li></ul></li></ul>	Section 4.3

This

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).

- ror 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 between the NVX-CoV2373 and placebo groups for the B strains (9.9 vs 9.7 and 9.9 vs 9.7 and 9.9 vs 38.1 for Yamagata) (Table 7). For the smaller of TVX o For the QIVc group, Day 21 HAI GMTs for the Influenza A H1N1 and H3N2 strains were numerically higher in the
- 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).
- 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.
- 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.

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).

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.

- 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).
- o Anti-S protein IgG SCRs in participants regardless of baseline SARS-CoV-2 serostatus in the NVX-CoV2373 group were 100.0% vs 99.2% for participants 65 to 84 years of age) to those reported in the Main Study. 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
  - 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).
  - 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

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...ent influenza vascine; CI - confidence interval; COVID.19 - coronavirus disease 2019; E.L.
...millitter; GMLR - geometric mean fold rise; GMT - geometric mean titer; BACE2 - human angio.
...mana immunodeficiency virus; IgG = immunoglobulic (g; VVX-CoV2373 - 5 µg SARS-CoV-2 G with 50 µ,
...madipvaneto; SARS-CoV-2 G with 50 µ,
...potein nanoparticle vascine; SCR - seroconversion rate; SRR - seroconversion rate; Thi - Type IT helper; Th2 - Type 2 They.
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In each of these clinical studies are summarized in Table 2.5-3. immunosorbent assay; EU/mL = ELISA units per milliliter; GMFR = geometric mean fold rise; GMT = geometric mean titer; hACE2 = human angiotensin-converting enzyme 2014. HAI = hemagglutination inhibition; HIV = human immunodeficiency virus; IgG = immunoglobulin G: NVX-CoV2373 = 5 ug SAPS CoV 2 rs with 50 up NVX-CoV2373 = 5 ug SAPS QIVc = quadrivalent influenza vaccine (unadjuvanted); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome

## 2.5.5.3

- 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 2010 (Part 1), induced robust immune response administered 21 days (+ 7 days) apart as a bedside mixture in Clinical Study 2019ncoV-101 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
- 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) and elicited a robust anti-S protein IgG response versus placebooks by approximately 30% in comparison vaccine on P 2019nCoV-302 showed that there was no statistically significant effect of NVX-CoV2373 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.

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#### 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 adjuvent 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.

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2019nCoV-501, Section 2 of Clinical Study 2019nCoV-501, and Section 2 of Clinical Study 2019nCoV-501, and Section 2 of Clinical Study 2019nCoV-501.

A pooled spale

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).

#### **Nonclinical Information Related to Safety** 2.5.6.2

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, fibringen, 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-ug and 25-ug 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.

## **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	2019n(	CoV-101	2019nCoV-501	2019nCoV-302 2019nCoV-301						
1	Part 1 <sup>1</sup>	Part 2 <sup>2</sup>		275						
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 coronavins 2 recombinant spike protein nanoparticle vaccine.

- 1. Group C (5 μg SARS-CoV-2 rS with 50 μg Matrix-M adjuvant on Days o and 21 [+ 7 days]) only.
- 2. Groups B (5 μg SARS-CoV-2 rS with 50 μg Matrix-M adjuvent on Days 0 and 21 [+ 7 days]) and C (5 μg SARS-CoV-2 rS with 50 μg Matrix-M adjuvent 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	2019nC (Par		2019nC (Par		2019nC	oV-501 <sup>3</sup>	2019nC	oV-302 <sup>4</sup>	2019nG	2019nCoV-301	
Trial Vaccine Group	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo	
N1/N2	26/26 <sup>5</sup>	23/21	508/250 <sup>6</sup>	252/242	2211/2141	2197/2124	1285/1203	1272/1172	18072/17139	8904/8278	
Any local TEAE								ten	(2)		
Dose 1 (Grade $\geq 1$ )	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	BILL	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	2.00 V	00 00	0	0	7 (0.04)	1 (0.01)	
Pain	Grade 4 0 0 0 0 0 0 0 0 0 0 0 0 7 (0.04) 1 (0.01)  Pain  Dose 1 (Grade $\geq$ 1) 10 (38.5) 3 (13.0) 139 (27.4) 10 (4.0) 393 (26.9) 261 (11.9) 394 (30.7) 130 (10.2) 6211 (34.37) 986 (11.07)  Grade 3 0 0 0 0 0 23 (1.0) 4 (0.2) 1 (<0.1) 1 (<0.1) 55 (0.30) 3 (0.03)										
Dose 1 (Grade $\geq 1$ )	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		23 (1.0)	4 (0.2)	1 (< 0.1)	1 (< 0.1)	55 (0.30)	3 (0.03)	
Grade 4	0	0	0	retion.	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	0,000	0	0	0	0	0	0	5 (0.03)	1 (0.01)	
Tenderness		0 <sub>port</sub>									
Dose 1 (Grade $\geq 1$ )	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	USE	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 31	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	

This

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	2019nC (Par			2019nCoV-101 (Part 2) <sup>2</sup> 2019nCoV-501 <sup>3</sup> 2019nCoV-302 <sup>4</sup> 2019		2019nCoV-302 <sup>4</sup>		₩-301		
Trial Vaccine Group	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo
N1/N2	26/26 <sup>5</sup>	23/21	508/250 <sup>6</sup>	252/242	2211/2141	2197/2124	1285/1203	1272/1172	18072/17139	8904/8278
Erythema										
Dose 1 (Grade $\geq 1$ )	0	0	3 (0.6)	0	17 (0.8)	5 ( 0.2)	25 (1.9)	5 (9.4)	164 (0.91)	27 (0.30)
Grade 3	0	0	0	0	1 (< 0.1)	1 (< 0.1)	0 0	9/10	3 (0.02)	0
Grade 4	0	0	0	0	0	0	an Bh	0	0	0
Dose 2 (Grade $\geq 1$ )	2 (7.7)	1 (4.8)	12 (4.8)	0	34 (1.6)	32(0.1)	100 (8.3)	2 (0.2)	1138 (6.64)	29 (035)
Grade 3	0	0	3 (1.2)	0	0,,0	196/10	11 (0.9)	0	143 (0.83)	2 (0.02)
Grade 4	0	0	0	0	23.60 ×10	U 00	0	0	0	0
Swelling				(	ma.euro					
Dose 1 (Grade $\geq 1$ )	0	0	5 (1.0)	1 (0.4)	(8.0)	5 (0.2)	12 (0.9)	6 (0.5)	154 (0.85)	24 (0.27)
Grade 3	0	0	0	. 20 S	0	1 (< 0.1)	0	0	7 (0.04)	3 (0.03)
Grade 4	0	0	0	retion	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	0,000	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 O.T.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		oV-101 t 1) <sup>1</sup>	2019nCo (Part		2019nC	oV-501 <sup>3</sup>	2019nC	oV-302 <sup>4</sup>	2019nG	₩-301
Trial Vaccine Group	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo
N1/N2	26/26 <sup>5</sup>	23/21	510/2506	251/241	2210/2141	2196/2123	1281/1198	1273/1164	18072/17139	8904/8278
Any systemic TEAE								ten	2.	
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 (224)	82 (6.8)	16 (1.4)	2056 (12.00)	165 (1.99)
Grade 4	0	0	0	1 (0.4)	2.80°	$0 \sim 0$	1 (< 0.1)	0	21 (0.12)	5 (0.06)
Nausea or Vomiting	Grade 4 0 0 0 1 (0.4) 0 1 ( $<$ 0.1) 0 21 (0.12) 5 (0.06) Nausea or Vomiting  Dose 1 (Grade $\ge 1$ ) 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 (5.4) 67 (6.2) 67 (6.2) 7 (0.3) 0 0 17 (0.09) 7 (0.08)									
Dose 1 (Grade $\geq$ 1)	1 (3.8)	1 (4.3)	25 (4.9)	9 (3.6)	(6.2)	109 (5.0)	67 (5.2)	69 (5.4)	1152 (6.37)	488 (5.48)
Grade 3	0	0	1 (0.2)		4 (0.2)	7 (0.3)	0	0	17 (0.09)	7 (0.08)
Grade 4	0	0	0	retion.	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	any.	0	11 (0.5)	6 (0.3)	1 (< 0.1)	0	29 (0.17)	7 (0.08)
Grade 4	0	SUPPORT	0	0	0	0	0	0	7 (0.04)	2 (0.02)
Headache										
Dose 1 (Grade $\geq$ 1)	6 (23 <sub>4</sub> ) <sup>x</sup> (	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	USE	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 37	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)

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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	2019nC (Par	oV-101 t 1) <sup>1</sup>		2019nCoV-101 (Part 2) <sup>2</sup> 2019nCoV-501 <sup>3</sup> 2019nCoV-302 <sup>4</sup> 201		2019nG	019nCeV-301			
Trial Vaccine Group	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo
N1/N2	26/26 <sup>5</sup>	23/21	510/2506	251/241	2210/2141	2196/2123	1281/1198	1273/1164	18072/17139	8904/8278
Fatigue								ren	2.	
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)	139 (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 (07)	43 (3.6)	9 (0.8)	1419 (8.28)	108 (1.30)
Grade 4	0	0	0	0	19 (0.5) 10 (0.5)	$0 \sim 0$	0	0	4 (0.02)	3 (0.04)
Malaise				6	Marisath					
Dose 1 (Grade $\geq$ 1)	3 (11.5)	2 (8.7)	62 (12.2)	30 (12.0)	(7.4)	127 (5.8)	149 (11.6)	122 (9.6)	2660 (14.72)	1037 (11.65)
Grade 3	0	0	8 (1.6)	. 80 s	10 (0.5)	8 (0.4)	4 (0.3)	4 (0.3)	137 (0.76)	53 (0.60)
Grade 4	0	0	0	(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	SUPPORT	0	0	0	0	0	0	9 (0.05)	2 (0.02)
Muscle pain										
Dose 1 (Grade $\geq$ 1)	6 (234)	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	USE	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)

This

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) <sup>1</sup>		2019nCoV-101 (Part 2) <sup>2</sup>		2019nCoV-5013   2019nCo		2019nCoV-302 <sup>4</sup>		2019nC	W-301
Trial Vaccine Group	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo
N1/N2	26/26 <sup>5</sup>	23/21	510/250 <sup>6</sup>	251/241	2210/2141	2196/2123	1281/1198	1273/1164	18072/17139	8904/8278
Joint pain										
Dose 1 (Grade $\geq 1$ )	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 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 $\geq 1$ )	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	23.80° ~;(	00 D	0	0	6 (0.04)	2 (0.02)
Fever				(	ema.eur					
Dose 1 (Grade $\geq$ 1)	0	0	12 (2.4)	6 (2.4)	(1.5)	32 (1.5)	28 (2.3)	19 (1.5)	66 (0.37)	33 (0.37)
Grade 3	0	0	3 (0.6)	. 20 3	5 (0.2)	7 (0.3)	5 (0.4)	2 (0.2)	8 (0.04)	6 (0.07)
Grade 4	0	0	0	(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	0,000	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.
- Group C only.

  Groups B and C only.

  Based on Table 14.3.2 12.3 of the 2019nCoV-501 Interim Report.
- Solicited local and systemic TEAEs were evaluated in a subset of 2,714 participants in this study.
- Excludes 3 sentinel participants who received active vaccine in an open-label manner.
- Based on Group B only as participants in Group C received placebo for their second vaccination.

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

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 TEAEs, tended to be reported at a higher frequency in the placebo group. Most unsolicited TEAEs 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

Deen to None of dy vaccination dy vaccination and the state of the sta

Unsolicited Adverse Event	2019nC (Par			2019nCoV-101 (Part 2) <sup>2</sup>		CoV-501	2019nC	loV-302	2019nCoV-\$01	
Parameters	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX	Placebo	NVX(\Q	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 <sup>4</sup>	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 <sup>5</sup>	0	0	0	0	2 (< 0.1)	2 (< 0.1)	2 (< 0.1)	1 (< 0.1)	9 (0.5)	5 (0.5)
Related <sup>6</sup>	0	0	0	0	0	oito	0	0	0	0
Any SAEs <sup>5</sup>	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 <sup>6</sup>	0	0	1 (0.2)	0	7718016	96 <sub>6</sub> 0	0	0	2 (< 0.1)	0
Any TEAEs leading to vaccination discontinuation <sup>5</sup>	0	0	4 (0.8)	4 (1.6)	risation	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	0	7 (< 0.1)	8 (0.1)	10 (0.1)	3 (< 0.1)
Any TEAEs leading to study discontinuation <sup>5</sup>	0	0	70	(0.8)	4 (0.2)	4 (0.2)	17 (0.2)	16 (0.2)	60 (0.3)	13 (0.1)
Related	0	0	Dr/Ke	0	0	1 (< 0.1)	5 (< 0.1)	2 (< 0.1)	14 (0.1)	2 (< 0.1)
MAAEs <sup>5</sup>	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 <sup>5</sup>	0	200	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 <sup>5</sup>	الاي 0	$b_{b}$ 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 = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; TEAE = treatment-emergent adverse event.

- 1. Group C only.
- Groups B and C only not b' Excludes 3 senting participants who received active vaccine in an open-label manner.
- 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).
- Events reported as of the data cutoff date for each respective study.
- According to both the investigator and the sponsor.
- Based on investigator's discretion.
- Revised PIMMC definition: PIMMC events identified via preferred term, per protocol.
- 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 requencies 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 Apalysis 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 pixotal Phase 3 efficacy studies, 2019nCoV-302 (UK) and 2019nCoV-301 (US and Mexics), 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<sup>TM</sup> 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 placeho 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 (Rable 2.5-14).

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

Study Number		NVX-CoV2373	Placebo
2019nCoV-101		543	278
2019nCoV-101 - Part 11	o)	29	23
2019nCoV-101 - Part 2 <sup>2</sup>		xi(1) 514	255
2019nCoV-501 <sup>3</sup>	X	2211	2197
2019nCoV-302 <sup>4</sup>	20,	7575 <sup>5</sup>	7564 <sup>5</sup>
2019nCoV-301	76	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

- Included Groups A (placebo) and C (two-dose regimen of 5 µg SARS-CoV-2 rS with 50 µg Matrix-M Adjuvant) only.
- 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.
- 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

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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 <sup>1</sup>	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 esevere acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

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

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  $\geq$  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	Placebo N = 19892	Total N = 49950
Dix.	n (%)	n (%)	11 - 45500
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)	S 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 ( $\geq 65$  years of age) reported a lower frequency and intensity of solicited local and systemic TEAEs than participants in the younger age cohort (18 to  $\leq$  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** 

, c	NVX-Co	V2373	Plac	cebo
Solicited Local and Systemic Adverse Events	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

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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						
	NVX-Co	V2373	Plac	cebo		
Solicited Local and Systemic Adverse Events	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)	(<0.01)	2 (0.02)		
Grade 4	0	0	0	0		
Swelling (Grade $\geq 1$ )	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	000	0	0		
Solicited systemic adverse ever	nts	7 20				
Any systemic (Grade ≥ 1)	9239 (47.54)	12295 (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 $\geq 1$ )	1284 (6.61)	2068 (11.28)	638 (5.72)	542 (5.17)		
Grade 3	22(0.110)	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 $\geq 1$ )	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 $\geq 1$ )	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 <sup>f</sup>	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** 

	NVX-Co	V2373	Plac	ebo
Solicited Local and Systemic Adverse Events	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** 

	NVX-Co	oV2373	Placebo		
Solicited Local and Systemic	Dose 1	Dose 2	Dose 1	Dose 2	
Adverse Events	N = 2673	N = 2392	N = 1498	N = 1346	
	Dose 1 N = 2673 n (%)	n (%)	n (%)	n (%)	
Solicited local adverse events	20. JU				
Any local (Grade $\geq 1$ )	994 (37.19)	1448 (60.54)	216 (14.42)	188 (13.97)	
Grade 3	n (%) 994 (37.19) 15 (0.56)	62 (2.59)	3 (0.20)	3 (0.22)	
Grade 4	X.	0	0	0	
Pain (Grade $\geq 1$ )	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 $\geq 1$ )	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 3 Grade 4	0	0	0	0	
Erythema (Grade ≥ t√)	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 (Crade $\geq 1$ )	18 (0.67)	139 (5.81)	1 (0.07)	7 (0.52)	
Coade 3	1 (0.04)	10 (0.42)	0	1 (0.07)	
Grade 4	0	0	0	0	
Solicited systemic adverse ever	nts				
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 $\geq 1$ )	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

	NVX-Co	V2373	Plac	ebo o
Solicited Local and Systemic	Dose 1	Dose 2	Dose 1	Dose 2
Adverse Events	N = 2673	N = 2392	N = 1498	$_{\circ}$ N = 1346
	n (%)	n (%)	n (%)	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)	(0.33)	14 (1.04)
Grade 4 <sup>f</sup>	0	0	Ø 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	0.0	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 00	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	(O) O)	1 (0.04)	0	0
Fever (Grade ≥ 1)	18 (0.67)	45 (1.88)	12 (0.80)	12 (0.89)
Grade 3	2 (007)	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  $\geq$  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.

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Table 2.5-18: Frequencies of Unsolicit Vaccination Through 28 of Participants in the Po	ted Adverse Eve 8 Days After Se poled Analysis o	ents Reported cond Vaccina of Safety Data	from After Sta tion (eg, Day 49	art of First ) in ≥ 0.5%
	Participants 18	to ≤ 64 Years	Participants 2	≥ 65 Years
System Organ Class/Preferred Term (MedDRA Version 23.1)	NVX- CoV2373 N = 25282	Placebo N = 16433	NVX- CoV2373 N = 4776	Placebo N = 3459
Any unsolicited TEAE	4627 (18.30)	2577 (15.68)	1083 (22,58)	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)	(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  $\geq 0.5\%$ of Participants in the Pooled Analysis of Safety Data

	Participants 18 to ≤ 64 Years		Participants ≥ 65 Yea	rs
System Organ Class/Preferred Term (MedDRA Version 23.1)	NVX- CoV2373 N = 25282	Placebo N = 16433	NVX- CoV2373 N = 4776 N = 3	
Metabolism and nutrition disorders	86 (0.34)	65 (0.40)	26 (0.59) 8 (0.3	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 = seere 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 amblinded 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

S	Participants 18	to ≤ 64 Years	Participants	≥ 65 Years
System Organ Class/Preferred Term (MedDRA Version 23.1)	NVX- CoV2373 N1 = 25282	Placebo N1 = 16433	NVX- CoV2373 N1 = 4776	Placebo N1 = 3459
Total followup 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

	Participants 18	to ≤ 64 Years	Participants ≥ 65 Years	
System Organ Class/Preferred Term (MedDRA Version 23.1)	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	E.C.	0
Septic shock	1 (0.02)	0	(°0	0
COVID-19	0	2 (0.05)	$(0.09)^3$	1 (0.12)
Bacterial sepsis	0	0	<b>o</b> 0	1 (0.12)
Injury, poisoning and procedural complications	1 (0.02)	0	1 (0.09)	0
Gunshot wound	1 (0.02)	· OX	0	0
Poisoning deliberate	0	<i>5</i> 110	1 (0.09)	0
Nervous system disorders	0	20° 0	1 (0.09)	0
Cerebrovascular accident	000	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 MedbRA = 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, sever acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

- This analysis censored 1 participant in the NXX-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).
- 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.
- 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 ( $\ge 65$  years of age). In the younger age cohort (18 to  $\le 64$  years), there were 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 currhosis 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

	Participants 18	to 64 Years	Participants ≥ 65 Years		
System Organ Class/Preferred Term (MedDRA Version 23.1)	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)	093	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 (122) Clinical Trials with an Incidence Rate > 0.10 e/100 PY in the Pooled Analysis of Safety Data

of Safety Data				,D	
	Participants 18	3 to ≤ 64 Years	Participants ≥ 65 Years		
System Organ Class/Preferred Term (MedDRA Version 23.1)	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)	(0.00)	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)	0.00)	0 (0.00)	1 (0.12)	
Nausea	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.12)	
Obstructive pancreatitis	0 (0.90)	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	(00.00)	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	(0.00)	0 (0.00)	0 (0.00)	1 (0.12)	
Psychiatric disorders	2 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 (ancl 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

	Participants 18	3 to ≤ 64 Years	Participants ≥ 65 Years	
System Organ Class/Preferred Term (MedDRA Version 23.1)	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 (0,09)	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)	0.00)	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 (0.93)	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	(0.00)	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.

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

## 2.56.7.8 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

<sup>1.</sup> 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).

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  $\leq$  64 years of age but numerically lower than in the placebo group among participants  $\geq$  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

	Participants 18 to ≤ 64 Years		Participants ≥ 65 Years	
System Organ Class/Preferred Term (MedDRA Version 23.1)	NVX- C6V23/3 N = 2\$282	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** 

	Participants 18	to ≤ 64 Years	Participants ≥ 65 Years	
System Organ Class/Preferred Term (MedDRA Version 23.1)	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)	000	0	0
Rheumatoid arthritis	1 (0.02)	2 (9.05)	1 (0.09)	1 (0.12)
Arthritis reactive	0	(0.02)	0	0
Eye disorders	4 (0.06)	(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	(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 ug SARS-CoV-2 rS with 50 ng Matrix-M adjuvant; PIMMC = potential immune-mediated medical condition; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

ore: Results are prese Source: T46.1.1, T46.1.2 Note: Results are presented as number of events per 100 person-years, with the event rate in parentheses.

## **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  $\mu$ g SARS-CoV-2 rS with 50  $\mu$ g Matrix-M adjuvant), administered 21 days (+ 7 days) apart, was well tolerated with no safety concerns in adult participants  $\geq$  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  $\mu$ g per dose) with Matrix-M adjuvant (50  $\mu$ g 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 assevere 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  $\geq$  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  $\geq$  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<sup>+</sup> 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 Nower 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  $\geq$  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  $\leq$  64 years and 6.74 active vs 6.60 placebo in participants  $\geq$  65 years). Lastly, incidence rates of PIMMCs were overall comparable with slightly higher rates in participants 18 to  $\leq$  64 years receiving NVX-CoV2373 (0.57 active versus 0.39 placebo), while the opposite trend was observed in participants  $\geq$  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<sup>+</sup> 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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#### 2.5.8 REFERENCES

Cele S, Gazy I, Jackson L, et al. Escape of SARS-CoV-2 501Y.V2 from neutralization by convalescent plasma. Nature. 2021 May;593(7857):142-146

Center for Disease Control and Prevention (CDC). SARS-CoV-2 Variant Classifications and Definitions. Updated June 29, 2021. Retrieved 02 July 2021. https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html.

COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed [11 August 2021].

Cucinotta D, Vanelli M. WHO Declares COVID-19 a Pandemic Acta Biomed. 2020 Mar 19;91(1):157-160.

Department of Health and Human Services (DHHS), Food and Drug Administration, Center for Biologics Evaluation and Research (US). Guidance for industry: Toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical trials. September 2007 [cited 2020 Apr 01]. Available from: https://www.fda.gov/media/73679/download

Formica N, Mallory R, Albert G, et al. Evaluation of a SARS-CoV-2 Vaccine NVX-CoV2373 in Younger and Older Adults. medRxiv 2021.02.26.21252482

Greaney AJ, Loes AN, Crawford KHD, et al. Comprehensive mapping of mutations in the SARS-CoV-2 receptor-binding domain that affect recognition by polyclonal human plasma antibodies. Cell Host Microbe. 2021 Mar 10;29(3):463-476.e6.

Habibzadeh P, Stoneman EK. The novel coronavirus: a bird's eye view. Int J Occup Environ Med. 2020;11(2):65-71

Heath PT, Galiza EP, Baxter DN, et al. Safety and Efficacy of NVX-COV2373 Covid-19 Vaccine. N Eng JMed. 2021 Jun 30;NEJMoa2107659.

Ho D, Wang P, Liu L, et al. Increased Resistance of SARS-CoV-2 Variants B.1.351 and B.1.1.7 to Antibody Neutralization. Res Sq [Preprint]. 2021 Jan 29:rs.3.rs-155394.

Lövgren-Bengtsson K, Morein B. Chapter 14: The ISCOM™ Technology. From: Methods in Molecular Medicine, Vol. 42. In: Vaccine Adjuvants: Preparation Methods and Research Protocols. O'Hagan DT (ed); Humana Press Inc., Totowa, NJ. 2000; 239-58.

Johnson Ja. Johnson & Johnson Announces Single-Shot Janssen COVID-19 Vaccine Candidate Met Primary Endpoints in Interim Analysis of its Phase 3 ENSEMBLE Trial. 2021. Keech C, Albert G, Cho I, et al. Phase 1-2 Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine [published online ahead of print, 2020 Sep 2]. N Engl J Med 2020;10.1056/NEJMoa2026920. doi:10.1056/NEJMoa2026920

Kimura I, Kosugi Y, Wu J, et al. SARS-CoV-2 Lambda variant exhibits higher infectivity and immune resistance. bioRxiv 2021.07.28.454085.

Madhi SA, Baillie V, Cutland CL, et al. Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1.351 Variant. N Engl J Med. 2021 May 20;384(20):885-1898.

National Institutes of Health (NIH). Coordinated strategy to accelerate multiple COVID-19 vaccine candidates is key, NIH experts say. 11 May 2020. [cited 23 May 2020]. Available from: https://www.nih.gov/news-events/news-releases/coordinated-strategy-accelerate-multiple-covid-19-vaccine-candidates-key-nih-experts-say

Reimer JM, Karlsson KH, Lövgren-Bengtsson K, Magnusson SE, Fuentes A, Stertman L. Matrix-M<sup>TM</sup> adjuvant induces local recruitment, activation and maturation of central immune cells in absence of antigen. PLoS One. 2012;7(7):e41451.

Sabino EC, Buss LF, Carvalho MPS, et al. Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence. Lancet. 2021 Feb 6;397(10273):452-455.

Shinde V, Bhikha S, Hoosain Z, et al. Efficacy of NVX-CoV2373 Covid-19 Vaccine against the B.1.351 Variant. N Eng J Med. 2021 May 20;384(20):1899-1909.

Starr TN, Greaney AJ, Hilton SK, et al. Deep Mutational Scanning of SARS-CoV-2 Receptor Binding Domain Reveals Constraints on Folding and ACE2 Binding. Cell. 2020 Sep 3;182(5):1295-1310.e20.

Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol. 2016;24(6):490-502.

Tegally H, Wilkinson E, Giovanetti M, et al. Detection of a SARS-CoV-2 variant of concern in South Africa. Nature. 2021 Apr;592(7854):438-443.

Tian JH, Patel N, Haupt R, et al. SARS-CoV-2 spike glycoprotein vaccine candidate NVX-CoV2373 mmunogenicity in baboons and protection in mice. Nat Commun. 2021 Jan 14;12(1):372.

Volz E, Mishra S, Chand M, et al. Assessing transmissibility of SARS-CoV-2 lineage B.1.1.7 in England. Nature. 2021 May;593(7858):266-269.

Wang Z, Schmidt F, Weisblum Y, et al. mRNA vaccine-elicited antibodies to SARS-CoV-2 and circulating variants. Nature. 2021 Apr;592(7855):616-622.

World Health Organization (WHOa). COVID-19 Weekly Epidemiological Update. Edition 44, published 15 June 2021. Retrieved 18 June 2021, from https://www.who.int/publications/m/item/weekly- epidemiological-update-on-covid-19-june-2021

World Health Organization (WHOb). Recommended composition of influenza viros vaccines for use in the 2020-2021 northern hemisphere influenza season. 18 February 2020. Accessed on 02 August 2021. https://www.who.int/publications/m/item/recommended composition-of-influenza-virus-vaccines-for-use-in-the-2020-2021-northern-hemisphere-influenza-season

Wibmer CK, Ayres F, Hermanus T, et al. SARS-CoV-2 501Y.V2 escapes neutralization by South African COVID-19 donor plasma. Nat Med. 2021 Apr;27(4):622-625.

Wrapp D, Wang N, Corbett KS, et al. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. Science. 2020;367(6483):1260-3.

Zou G. A modified poisson regression approach to prospective studies with binary data. Am J Epidemiol. 2004;159(7):702-706.

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SARS-CoV-2 rS	with Matrix-M Adjuvant
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SARS-CoV-2 rS Novavax, Inc.	with Matrix-M Adjuvant Confidential	2.5 Clinical Overvio
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### Table 1 Summary of Clinical Trials and the Number of Participants Included in the Integrated Summary of Safety

			any extensio	Included in the Summary of Vaccine	of Safety
		Treatment Groups	ansio	SARS-CoV-2 rS	
		(Dose 1 at Day 0 + Dose 2 at Day 21) V = SARS-CoV-2 rS vaccine	exter	(ɔμg) + Matrix-M1	
Study Number	Study Design	M = Matrix-M1 adjuvant	Yns	adjuvant	
(Country)	(Randomization ratio)	P = Placebo		(50µg)	Placebo
2019nCoV-101 - Part 1	Phase 1, randomized, observer-blinded,	A: P + P			23
(Australia)	placebo-controlled in healthy adults >= 18 to <=	A: P + P B: V (25µg) and M (0µg) + V(25µg) and M (0µg)		(Group C)	(Group A
	59 years of age	C: V (5µg) and M (50µg) P V (5µg) and M (50µg)			
	(1:1:1:1)	D: V (25μg) and M (50μg) + W (25μg) and M (50μg)			
		E: V (25µg) and M (50µg) + P  A: P + P			
2019nCoV-101 - Part 2	Phase 2, randomized, observer-blinded,	A: P+P + NOTTS		514	255
(Australia and US)	placebo-controlled in healthy adult subjects >= 18	B: V (5µg) and M (50µg) + V (5µg) and M (50µg)		(Groups B and	(Group A
	to < 85 years of age	6. V (5μg) and M (50μg) + P		C)	
	(1:1:1:1:1)	D: V (25µg) and M (50µg) + V (25µg) and M (50µg)			
	ay Mic	E: V (25µg) and M (50µg) + P			
	Phase 2, randomized, observer-blinded, placebo-controlled in healthy adult subjects >= 18 to < 85 years of age (1:1:1:1:1)  Im t_pop_sas 17JUL2021 08:17				
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### Table 1 Summary of Clinical Trials and the Number of Participants Included in the Integrated Summary of Safety

			Number o Included in Summar	Participants the Integrate y 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  A: P + P B: V (5µg) and M (50µg) V (5µg) and M (50µg)  A: P + 8  A: P + 8  C (5µg) and M (50µg) + V (5µg) and M (50µg)	Vaccine SARS-CoV-2 rS (5µg) + Matrix-M1 adjuvant (50µg)	S 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 B: V (5μg) and M (50μg) V (5μg) and M (50μg)	2,211	2,197
2019nCoV-302 (United Kingdom)	(Randomization ratio)  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)  Phase 3, randomised, observer-blinded, placebo-controlled trial in adults 18 to 84 years (1:1)  from t_pop.sas 174012021 08:17	А: P + 8 V (5µg) and M (50µg) + V (5µg) and M (50µg)	7,575	7,564
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### Table 1 Summary of Clinical Trials and the Number of Participants Included in the Integrated Summary of Safety

/-101 Part1/2019r	CoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCo  Table 1 Summary of Clinical Trials and the	V-501 Number of Participants Included in the Integrated	Page 3 of 3 Summary of Safety	ş.*.	ions there
				Number of P	articipants Integrated
udy Number ountry)	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	any extensio	Vaccine SARS-CoV-2 rS (5µg) + Matrix-M1 adjuvant (50µg)	Placebo
I9nCoV-301 , Mexico)	Phase 3, randomized, observer-blinded, placebo-controlled Study to in adults >= 18 years of age (2:1)	V = SARS-CoV-2 rS vaccine M = Matrix-M1 adjuvant P = Placebo  A: P + P B: V (5µg) and M (50µg) PV (5µg) and M (50µg)		19,729	9,853
tal	arke	eting authoris		30,058	19,892

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

Umber of Doses Received  SARS-CoV-2 rs (Syug) + Matrix-M1 adjuvant (SQug)  we doses 28 963 10,075 cotal  19,270 nee dose 1,095 cotal  30,058  articipants receiving a mixed regimen are included in the ISS as receiving 1 dose of the active vaccine and any side of short-term safety post the second dose of the active vaccine a Name: 12-rtf. Generated from Lexp sas 17,JUL2021 08:18  Number of Participants included in the Safety Analysis  Vaccine SARS-CoV-2 rs (Syug) + Matrix-M1 adjuvant (SQug)  19,270 nee dose 19,270 nee dose 19,892 19,892 19,892  articipants receiving a mixed regimen are included in the ISS as receiving 1 dose of the active vaccine and any side of the active v			مج زار
who doses dose received adjuvant (50µg) Hatrix-M1 (50µg) Hatrix		Number of Participants Ir	ncluded in the Safety Analysis
tumber of Doses Received  adjuvant (50µg)  wo doses  the dose'  1,095'  28,963  30,058  articipants receiving a mixed regimen are included in the ISS as receiving 1 dose of the active vaccine and only be what a post the active vaccine dose are included in the analysis. They will not be a Name: 12,rtf. Generated from 1_exp.sas 17JUL2021 08:18  This document cannot be used to support any marketing authorisation.		Vaccine	ariae
Jumber of Doses Received  adjuvant (Supp)  28 963 28 963 1,095* 1,095* 1,095 10 30,058  articipants receiving a mixed regimen are included in the ISS as receiving 1 dose of the active vaccine and only the other post the active vaccine dose are included in the analysis. They will not be a Name: 12.rtf. Generated from 1_exp.sas 17JUL2021 08:18  This document cannot be used to support any marketing authorisation.		SARS-CoV-2 rS (5µg) + Matrix-M1	or Va
we doses 1,963 1,995 622 otal 30,058 1,995 extends of 19,270 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 the analysis of short-term safety post the second dose of the active vaccine a Name: t2.rtf. Generated from t_exp.sas 17,012021 08:18  This document common to be used to support any marketing authorises.	Number of Doses Received	adjuvant (50µg)	Placebo
of all 30,058  1,095° and and any extent 622 of 19,892  articipants receiving a mixed regimen are included in the ISS as receiving 1 dose of the active vaccine and any extent 622 of 19,892 and any extent 622 of 19,892 and any extent 622 of 19,892	Two doses	28,963	25i <sup>01</sup> 19,270
articipants receiving a mixed regimen are included in the ISS as receiving 1 dose of the active vaccine and only the pala post the active vaccine dose are included in the analysis. They will not the analysis of short-term safety post the second dose of the active vaccine and only the pala post the active vaccine dose are included in the analysis. They will not the analysis of short-term safety post the second dose of the active vaccine and only the pala post the active vaccine dose are included in the analysis. They will not the analysis of short-term safety post the second dose of the active vaccine and only the pala and any analysis of short-term safety post the active vaccine dose are included in the analysis. They will not the analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis. They will not the analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis. They will not the analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis. They will not the active vaccine and any analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis. They will not the active vaccine and any analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis. They will not the active vaccine and any analysis of short-term safety post the active vaccine and any analysis. They will not the active vaccine and any analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine and any analysis of short-term safety post the active vaccine	One dose*	1,095*	tel 622
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Table 3 Demographic Characteristics of Participants Included in the Integrated Summary of Safety

	Vaccine (n, %)	Placebo (n, %)	rions III
emographic Characteristics	N = 30058		Total N = 49950
ge			25 0,
18-64	25282 (84.11)	16433 (82.61)	41715
>= 65	4776 (15.89)	3459 (17.39)	8235
sender		N = 19892 16433 (82.61) 3459 (17.39) 10364 (52.30) any	
Male	15826 (52.65)	10364 (52.10)	26190
Female	14232 (47.35)	9528 (47.90)	23760
ace	15826 (52.65) 14232 (47.35) 22415 (74.57) 4417 (14.69) 1119 (3.72) 1322 (4.40) 58 (0.19) 463 (1.54)	od.eu dicatio	
White	22415 (74.57)	14808 (74.44)	37223
Black or African American	4417 (14.69)	3256 (16.37)	7673
Asian	1119 (3.72) en isa	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) 13 (0.14) 12 (0.04)	134 (0.67)	343
Other	43 (0.14)	54 (0.27)	97
Missing	12 (0.04)	11 (0.06)	23

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

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Tab	le 3 Demographic Characteristics of Participants Inclu	ded in the Integrated Summary of Safety	inns thei
Demographic Characteristics	Vaccine (n, %) N = 30058	Placebo (n, %) N = 19892	Total N = 49950
Ethnicity Hispanic/Latino Not Hispanic/Latino Not Reported Unknown Missing	4463 (14.85) 24647 (82.00) 780 (2.59) 161 (0.54) 7 (0.02)	2262 (11.37) 16747 (84.19) 726 (3.65) 152 (0.76) 5 (0.03)	6725 41394 1506 313 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)

			410,
	Vaccine	Placebo	Wisk Difference
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
	N = 19436	N = 11153	(%, 95% CI)
ny solicited local reactogenicity AEs	11192 (57.58), (56.89, 58.28)	(n, %, 95% CI) N = 11153 2296 (20.59), (19.84, 21.35) 1840 (16.50) 427 (3.83)	35.55 (34.53, 36.58)
Mild	7762 (39.94)	1840 (16.50)	,
Moderate	3200 (16.46)	427 (3.83)	
Severe	220 (1.10)	20 (0.25)	
Potentially Life Threatening	1 (<0.01)	1(20:01)	
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ain	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)	26 (0.25) 1 (0.01) 1276 (11.44), (10.86, 12.05) 1203 (10.79) 66 (0.59) 7 (0.06) 0 1752 (15.71), (15.04, 16.40)	
Severe	75 (0.39)	7 (0.06)	
Potentially Life Threatening	o ell risaci	0	
y a see y	*HO1,		
enderness	9902 (50.95), (50.24, 53.65)	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)	
		19 (0.17)	
Potentially Life Threatening	1 (<0.01)	1 (<0.01)	
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e: Risk difference and its Confidence Intervals (CIs	) are computed from Mantel-Haenszel Standardized Ris	sk Estimates and 95% normal confidence limits with	the stratification by study
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19nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 8.1.1_1.a Subgro</b> ւ	oV-301/2019nCoV-302/2019nCoV-501 up Summary of Local (Injection Site) Reactogenicity Adver (18-64 Years)	Page 2 of 2 se Events for Dose 1 (Day 0 to 6 Post Vaccination	on) By Age  Risk Difference
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI) N = 11153	Risk Difference (Vaccine - Placebo) (%, 95% Cl)
- Trythema	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 (20.01)	
Potentially Life Threatening	0	ion a o	
No. of History	170 (0.07) (0.75, 1.00)	1. EU 11 CATTO	0.57 (0.40, 0.74)
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 alitho	0	
	N = 19436  190 (0.98), (0.84, 1.13)  157 (0.81)  29 (0.15)  4 (0.02)  0  170 (0.87), (0.75, 1.02)  115 (0.59)  49 (0.25)  6 (0.03)  0  Is) are computed from Mantel-Haenszel Standardized Risk		
te: Risk difference and its Confidence Intervals (C	ls) are computed from Mantel-Haenszel Standardized Risk	Estimates and 95% normal confidence limits wit	h the stratification by study, wh
ividual group statistics are not adjusted by strata.  Name: t8_1_1_1_a.rtf. Generated from t_sol_sused  Linis document cannot be used	adhor sas 000 IC2021 14:14		
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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)

			410.
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
	N = 18340	(n, %, 95% CI) N = 10488	(%, 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)	32 (0.31) 32 (0.31) 32 (0.01) 32 (0.01) 32 (0.01) 1217 (11.96, 13.24) 1217 (11.60) 88 (0.84) 14 (0.13) 1 (<0.01)	
, , ,	•	· on a	
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) all 100 all	88 (0.84)	
Severe	340 (1.85) 2	14 (0.13)	
Potentially Life Threatening	5 (0.03)	1 (<0.01)	
, ,	*HOI,	,	
enderness	12731 (69.42), (68.74, 70.08)	1501 (14.31), (13.65, 15.00)	52.18 (51.26, 53.10)
	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	
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4 40	Support any market 5643 (30.77) 888 (4.84) 3 (0.02)		
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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)

Mild       467 (2.55)       18 (0.17)         Moderate       547 (2.98)       11 (0.10)         Severe       148 (0.81)       12 (0.02)         Potentially Life Threatening       0       0				orliae
rythema		Vaccine	Placebo	Risk Difference
rythema		(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
rythema		N = 18340	N = 10488	(%, 95% CI)
ividual group statistics are not adjusted by strata.	Erythema	1162 (6.34), (5.99, 6.70)	31 (0.30), (0.20, 0.42)	5.82 (5.46, 6.18)
ividual group statistics are not adjusted by strata.	Mild	467 (2.55)	18 (0.17)	
ividual group statistics are not adjusted by strata.	Moderate	547 (2.98)	11(0.10)	
ividual group statistics are not adjusted by strata.	Severe	148 (0.81)	(0.02)	
ividual group statistics are not adjusted by strata.	Potentially Life Threatening	0	0 0	
ividual group statistics are not adjusted by strata.	, o	e <sup>U</sup> · c	ation	
ividual group statistics are not adjusted by strata.	Swelling	1066 (5.81), (5.48, 6.16)	26 (0.25), (0.16, 0.36)	5.39 (5.04, 5.74)
ividual group statistics are not adjusted by strata.	Mild	551 (3.00) all of all of	16 (0.15)	
ividual group statistics are not adjusted by strata.	Moderate	427 (2.33) 2	9 (0.09)	
ividual group statistics are not adjusted by strata.	Severe	88 (0.48)	1 (<0.01)	
ividual group statistics are not adjusted by strata.	Potentially Life Threatening	0 *h01	0	
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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)

			410,
	Vaccine	Placebo	Kisk Difference
	(n, %, 95% CI)	(n, %, 95% CI) N = 1498 216 (14.42), (12.68, 16.30) 175 (11.68) 38 (2.54)	(Vaccine - Placebo)
	N = 2673	N = 1498	(%, 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	8/18 (31.72)	175 (11.68)	
Moderate	131 (4.90)	38 (2.54)	
Severe	15 (0.56)	3 (0, 26)	
Potentially Life Threatening	0	38 (2.54) 3 (0.26) 3 (0.26) 3 (0.26) 3 (0.26) 111 (7.41) 2 (0.13) 1 (0.07) 0 170 (11.35), (9.79, 13.06) 132 (8.81)	
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Pain	508 (19.00), (17.53, 20.54)	(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) ma stic	1 (0.07)	
Potentially Life Threatening	o ell'risac	0	
	'tho'		
enderness	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	91 (0.41)	2 (0.13)	
Potentially Life Threatening	0 //	0	
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- A *	752 (28.73) 117(4.38) 117 (0.41) 0 SUPPORT any 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)

(n, %, 95% CI) N = 2673 (N = 1498 (Waccine - Place (N, 95% CI) N = 1498 (Waccine - Place (Waccin				arlos
Mild 17 (0.64) 4 (0.27)  Moderate 3 (0.11) 1 (0.07)  Severe 0 0  Potentially Life Threatening 0 18 (0.67), (0.40, 1.06) 1 (0.07), (0.00, 0.37) 0.56 (0.24, 0.8)  Mild 10 (0.37) 1 (0.07)  Moderate 0 0  Swelling 18 (0.67), (0.40, 1.06) 1 (0.07), (0.00, 0.37) 0.56 (0.24, 0.8)  Mild 10 (0.37) 1 (0.07)  Moderate 7 (0.26) 0  Severe 1 (0.04) 0  Potentially Life Threatening 0 0		Vaccine	Placebo	Risk Difference
Mild 17 (0.64) 4 (0.27)  Moderate 3 (0.11) 1 (0.07)  Severe 0 0  Potentially Life Threatening 0 18 (0.67), (0.40, 1.06) 1 (0.07), (0.00, 0.37) 0.56 (0.24, 0.8)  Mild 10 (0.37) 1 (0.07)  Moderate 0 0  Swelling 18 (0.67), (0.40, 1.06) 1 (0.07), (0.00, 0.37) 0.56 (0.24, 0.8)  Mild 10 (0.37) 1 (0.07)  Moderate 7 (0.26) 0  Severe 1 (0.04) 0  Potentially Life Threatening 0 0		(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Mild 17 (0.64) 4 (0.27)  Moderate 3 (0.11) 1 (0.07)  Severe 0 0  Potentially Life Threatening 0 18 (0.67), (0.40, 1.06) 1 (0.07), (0.00, 0.37) 0.56 (0.24, 0.8)  Mild 10 (0.37) 1 (0.07)  Moderate 0 0  Swelling 18 (0.67), (0.40, 1.06) 1 (0.07), (0.00, 0.37) 0.56 (0.24, 0.8)  Mild 10 (0.37) 1 (0.07)  Moderate 7 (0.26) 0  Severe 1 (0.04) 0  Potentially Life Threatening 0 0		N = 2673	N = 1498	(%, 95% CI)
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studividual group statistics are not adjusted by strata	Erythema	20 (0.75), (0.46, 1.15)	5 (0.33), (0.11, 0.78)	0.40 (-0.05, 0.86)
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studividual group statistics are not adjusted by strata	Mild	17 (0.64)	4 (0.27)	
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studied group statistics are not adjusted by strata	Moderate	3 (0.11)	1 (0.07)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studioidal group statistics are not adjusted by strata.	Severe	0	300	
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studioidal group statistics are not adjusted by strata.	Potentially Life Threatening	0	:0000	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studioidal group statistics are not adjusted by strata.	•		eu catio	
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studied group statistics are not adjusted by strata	Swelling	18 (0.67), (0.40, 1.06)	1 (0.07), (0.00, 0.37)	0.56 (0.24, 0.88)
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studioidal group statistics are not adjusted by strata.	Mild	10 (0.37)	1 (0.07)	
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studividual group statistics are not adjusted by strata	Moderate	7 (0.26)	0	
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studividual group statistics are not adjusted by strata	Severe	1 (0.04) eli risa	0	
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studividual group statistics are not adjusted by strata	Potentially Life Threatening	0 'tho'	0	
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studividual group statistics are not adjusted by strata		a all		
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te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studividual group statistics are not adjusted by strata		, mar		
te: Risk difference and its Confidence Intervals (Cls) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by studividual group statistics are not adjusted by strata		201		
lividual group statistics are not adjusted by strata	ote: Risk difference and its Confidence Intervals (CIs)	are computed from Mantel-Haenszel Standardized Risk	Estimates and 05% normal confidence limits with	the stratification by study w
e Name: t8_1_2_1_a.rtf. Generated from t_sol_sum_adhoc.sas 09AUG2021 14:14	dividual group statistics are not adjusted by strata	are compared from Mariter-Hachszer Standardized Kisk	Estimates and 75% normal confidence limits with	the stratification by study, w
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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)

			*101
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
	N = 2392	N = 1340	(%, 95% CI)
Any solicited local reactogenicity AEs	1448 (60.54), (58.54, 62.50) 935 (39.09) 451 (18.85) 62 (2.59) 0  976 (40.80), (38.82, 42.80) 865 (36.16) 97 (4.06) 14 (0.59) 0  1324 (55.35), (53.33, 57.36) 892 (37.29) 397 (16.60) 35 (1.46) 0	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	200 0	
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ain	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) QUITO 3P	2 (0.15)	
Severe	14 (0.59)	1 (0.07)	
Potentially Life Threatening	Oell, risal	0	
· · · · · · · · · · · · · · · · · · ·	*H01,		
Tenderness	1324 (55.35), (53.33, 57.36) (892 (37.29) 397 (16.60) 35 (1.46) 0	127 (9.44), (7.93, 11.12)	45.05 (42.51, 47.5)
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	
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ividual 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)

			arlas
	Vaccine (n, %, 95% CI) N = 2392  125 (5.23), (4.37, 6.19) 45 (1.88) 71 (2.97) 9 (0.38) 0  139 (5.81), (4.91, 6.82) 62 (2.59) 67 (2.80) 10 (0.42) 0 uthorisation	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI) N = 1346	(Vaccine - Placebo)
	N = 2392	N = 1346	(%, 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)	200 0	
Potentially Life Threatening	0	:07 0	
	260:03	Clo	
welling	139 (5.81), (4.91, 6.82)	7 (0.52), (0.21, 1.07)	5.39 (4.35, 6.42)
Mild	62 (2.59) eul a a P	5 (0.37)	
Moderate	67 (2.80)	1 (0.07)	
Severe	10 (0.42)	1 (0.07)	
Potentially Life Threatening	0 '4\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0	
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ata: Pisk difference and its Confidence Intervals (CIs) are	computed from Mantel-Haenszel Standardized Risk Estimates and	1 05% normal confidence limits with	the stratification by study, w
lividual group statistics are not adjusted by strata.	compared from Mariter-Haeriszer Standardized Kisk Estimates and	2 7570 Horrital Cormachice littles With	the stratification by study, w
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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)

			*101.
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
	N = 19436	N = 11153	(%, 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)	
ever	121 (0.62), (0.52, 0.74)	234 (2.10) 6 (0.05) 234 (2.10) 6 (0.05) 21 (0.19) 21 (0.19) 14 (0.13) 2 (0.02) 1202 (10.78), (10.21, 11.37)	0.06 (-0.13, 0.25)
Mild	60 (0.31)	41 (0.37)	0.00 ( 0.13, 0.23)
Moderate	36 (0.19)	21 (0.19)	
Severe	19 (0.10)	14 (0.13)	
Potentially Life Threatening	6 (0.03) en risati	2 (0.13)	
Totermany Life Tricatering	5 (0.03) Shorts	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)	2.00 (2.10, 0.02)
Moderate	1119 (5.76)	485 (4.35)	
	745 (0.75)	61 (0.55)	
Potentially Life Threatening	8 (0.04)	2 (0.02)	
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te: Risk difference and its Confidence Intervals (CIs) a	re computed from Mantel-Haenszel Standardized Ris	sk Estimates and 95% normal confidence limits with	the stratification by study,
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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)

			3110
	Vaccine	Placebo (n, %, 95% CI) N = 11153	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
	N = 19436	N = 11153	(%, 95% CI)
atigue	4855 (24.98), (24.37, 25.59)	2278 (20.42), (19.68, 21.19)	3.29 (2.32, 4.26)
Mild	2414 (12.42)		
Moderate	2202 (11.33)	1022 (9.36)	
Severe	235 (1.21)	114(1.02)	
Potentially Life Threatening	4 (0.02)	1141 (10.23) 1022 (9.36) 114 (1.02) 1 (<0.01) 736 (6.60), (6.15, 7.08) 470 (4.21) 236 (2.12) 30 (0.27) 0	
		a eu .: catio	
oint 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) en risa	30 (0.27)	
Potentially Life Threatening	2 (0.01) th <sup>O</sup>	0	
	alle		
Muscle Pain		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)	
, ,	101 (0.52) 3 (0.02)  Cls) are computed from Mantel-Haenszel Standardized Ris	,	
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te: Risk difference and its Confidence Intervals (	CIs) are computed from Mantel-Haenszel Standardized Ris	sk Estimates and 95% normal confidence limits with	the stratification by study, w
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(n, %, 95% Cl) (Vaccine N = 19436 N = 11153 (%, 9 + 11153 (%, 9 + 11153) (%, 9 +	vavax, Inc I 9nCoV-101 Part1/2019nCoV-101 Part2/2019nCo' <b>Table 9.1.1_1.a Su</b>	V-301/2019nCoV-302/2019nCoV-501 Obgroup Summary of Systemic Reactogenicity Adverse Ev (18-64 Years)	Confidential Page 3 of 3 vents for Dose 1 (Day 0 to 6 Post Vaccination) By A	age  - or variations there Risk Difference
(In, %, 95% CI) (Na, 95% CI) (Vaccine N = 19436 N = 11153 (Waccine N = 11153 N = 11153 (Waccine N = 11153 N =		Vaccine	Placebo	Risk Difference
Headache			(n, %, 95% CI) N = 11153	(Vaccine - Placebo) (%, 95% CI)
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	leadache	4006 (25.24) (24.63.25.86)	2486 (22 20) (21 62 23 04)	2.32 (1.33, 3.32)
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Mild	3707 (19.07)	1896 (17.00)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Moderate	1037 (5.34)	507 (4.55)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Severe	157 (0.81)	82 (0.74)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Potentially Life Threatening	5 (0.03)	1) rion ((<0.01)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Nausea or Vomiting	1284 (6.61), (6.26, 6.96)	638 (5.72), (5.30, 6.17)	0.82 (0.26, 1.38)
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Mild	1014 (5.22)	495 (4.44)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Moderate	243 (1.25)	126 (1.13)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Severe	22 (0.11)	14 (0.13)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I	Potentially Life Threatening	5 (0.03) <sub>uth</sub> 0	3 (0.03)	
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I		iketing ac		
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I		'Wai,		
te: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification I		any		
ividual group statistics are not adjusted by strata.  Name: t9_1_1_a.rtf. Generated from t_sol_sub_adhoc.sas 09AUG2021 14:14  Lange to the cannot be used to the control of	e: Risk difference and its Confidence Intervals (CI	s) are computed from Mantel-Haenszel Standardized Risk	Estimates and 95% normal confidence limits with	the stratification by study, wh
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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)

			*10,
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
	N = 18340	N = 10488	(%, 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)	(0.06)	
, ,	,	· on or	
ever	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) all of the state of	10 (0.10)	
Severe	73 (0.40) 2	9 (0.09)	
Potentially Life Threatening	3(0.02)	1 (<0.01)	
3	4230 (23.06) 5826 (31.77) 2129 (11.61) 20 (0.11) 1046 (5.70), (5.37, 6.05) 683 (3.72) 287 (1.56) 73 (0.40) 3 (0.02) 6766 (36.89), (36.19, 37.60)	( /	
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)	
ed to sup	6766 (36.89), (36.19, 37.60) 2088 (11.38) 3584 (19.54) 1085 (5.92) 9 (0.05)		
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te: Risk difference and its Confidence Intervals (CIs) are co	mouted from Mantel-Haenszel Standardized Disk Estim	nates and 05% normal confidence limits with t	ho stratification by study w
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	oup Summary of Systemic Reactogenicity Adverse Events fo (18-64 Years)		ariations ther
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI) N = 10488	(Vaccine - Placebo)
	N = 18340	N = 10488	(%, 95% CI)
atigue	8592 (46.85), (46.12, 47.57)	1991 (18.98), (18.24, 19.25)	25.09 (24.06, 26.11)
Mild	2539 (13.84)	934 (8.91)	
Moderate	4624 (25.21)	935 (8.91)	
Severe	1425 (7.77)	3(179 (1.13)	
Potentially Life Threatening	4 (0.02)	3 (0.03)	
oint 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 (2.90)	31 (0.30)	
Potentially Life Threatening	4624 (25.21) 1425 (7.77) 4 (0.02)  3932 (21.44), (20.85, 22.04) 1688 (9.20) 1799 (9.81) 440 (2.90) 5 (0.03)	2 (0.02)	
Nuscle 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	8440 (46.02), (45.30, 46.74) 3870 (21.10) 3695 (20.15) 870 (4.74) 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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	group Summary of Systemic Reactogenicity Adverse Events for Do (18-64 Years)	· ·	or Variations there
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI) N = 18340	(n, %, 95% CI) N = 10488	(Vaccine - Placebo) (%, 95% CI)
leadache	7932 (43.25), (42.53, 43.97)	1930 (18.40), (17.66, 1936)	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)	
lausea or Vomiting	2068 (11.28), (10.82, 11.74) 00 <sup>2</sup> 00 <sup>1</sup>	542 (5.17), (4.75, 5.61)	5.71 (5.09, 6.34)
Mild	1477 (8.05)	408 (3.89)	, , ,
Moderate	545 (2.97) 2. 50	119 (1.13)	
Severe	39 (0 2) 3500	13 (0.12)	
Potentially Life Threatening	7 (0.04)	2 (0.02)	
	Vaccine (n, %, 95% CI) N = 18340  7932 (43.25), (42.53, 43.97) 4232 (23.08) 3140 (17.12) 555 (3.03) 5 (0.03)  2068 (11.28), (10.82, 11.74) 1477 (8.05) 545 (2.97) 39 (0.21) 7 (0.04)		
e: Risk difference and its Confidence Intervals (CIs)	are computed from Mantel-Haenszel Standardized Risk Estimates	and 95% normal confidence limits with th	e stratification by study, wh
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Page 1 of 3

### 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)

			41011
	Vaccine	Placebo	VIII) L DICC
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
	N = 2673	N = 1498	(%, 95% CI)
Any solicited systemic reactogenicity AEs	850 (31.80), (30.04, 33.60)	Placebo (n, %, 95% CI) N = 1498 445 (29.71), (27.40, 32.09) 281 (18.76) 149 (9.95)	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)	149 (9.95) 14 (0.93) 1(0.07)	
ever	263 (9.84), (8.74, 11.03)  265 (9.84)  101 (3.78)	2 2 2 (0 80) (0 41 1 40)	0.03 (-0.49, 0.56)
Mild	g (0.30)	6 (0.40)	0.03 (-0.47, 0.30)
Moderate	7 (0.36)	5 (0.33)	
Severe	2 (0.07)	1 (0.07)	
Potentially Life Threatening	1 (0.04) emission	1 (0.07)	
	1 (0.04)	Ü	
<i>M</i> alaise	263 (9.84), (8.74, 11.03)  147 (5.50)  101(3.78)  15 (0.56)  0  re computed from Mantel-Haenszel Standardized Ris	115 (7.68), (6.38, 9.14)	1.73 (-0.06, 3.51)
Mild	147 (5.50)	59 (3.94)	,
Moderate	10143.78)	51 (3.40)	
Severe	95 (0.56)	4 (0.27)	
Potentially Life Threatening	0	1 (0.07)	
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te: Risk difference and its Confidence Intervals (CIs) ar	so community of from Montal Hoomanal Ctandordinad Di	ok Estimates and OEO/ narmal confidence limits with	the stretification by study ,
te. Risk unference and its confidence intervals (cis) at	e computed from Mantel-Haeriszer Standardized Ki	sk estimates and 95% normal confidence limits with	the stratification by study, t
ividual group statistics are not adjusted by strata.			
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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			ario
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
	N = 2673	N = 1498	(%, 95% CI)
Fatigue	434 (16.24), (14.86, 17.69)	(n, %, 95% CI) N = 1498 213 (14.22), (12.49, 16.09) 110 (7.34) 98 (6.54)	1.18 (-1.09, 3.44)
Mild	221 (9.64)	110 (7.34)	· · · · · ·
Moderate	179 (6.70)	98 (6.54)	
Severe	24 (0.90)	5((0.33)	
Potentially Life Threatening	O ,	98 (6.54) 98 (6.54) 5 (0.33) 0 91 (6.07), (4.92, 7.41) 52 (3.47) 34 (2.27) 5 (0.33) 0	
, o		eu catio	
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) ellerisate	5 (0.33)	
Potentially Life Threatening	0 '4/0'	0	
3	adul		
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	ort at a	0	
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	sed to support any (2.51)		
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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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/avax, Inc 9nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV <b>Table 9.1.2_1.a Suk</b>	ogroup Summary of Systemic Reactogenicity Adverse Ev	Confidentia Page 3 of 3 vents for Dose 1 (Day 0 to 6 Post Vaccination) By	, here
	(>= 65 Years)		ziatio,
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI) N = 2673	(n, %, 95% CI) N = 1498	Risk Difference (Vaccine - Placebo) (%, 95% CI)
leadache	40F (1F 1F) (10 01 1/ F7)		-0.21 (-2.51, 2.08)
Mild	344 (12.87)	188 (12.55)	
Moderate	47 (1.76)	34 (2.23)	
Severe	13 (0.49)	4(0.27)	
Potentially Life Threatening	1 (0.04)	3//01211	
. otomany in outoning	. (6.6.7)	eu ation	
lausea 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)	(6.6.1, 2.22)
Moderate	16 (0.60)	8 (0.53)	
Severe	0 en sisali	0	
Potentially Life Threatening	0 */0//	0	
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	in <sup>9</sup>		
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	mal.		
	99 (3.70), (3.02, 4.49) 83 (3.11) 16 (0.60) 0 0 authorisation		<del></del>
	) are computed from Mantel-Haenszel Standardized Risk		
e: Risk difference and its Confidence Intervals (Cls	) are computed from Mantel-Haenszel Standardized Risk	Estimates and 95% normal confidence limits with	ı the stratification by study, whi
vidual group statistics are not adjusted by strata.	Supplied from Walter Haeriszer Standardized Kisk		
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### 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)

			*10,
	Vaccine	Placebo	Risk Difference
	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo
	N = 2392	N = 1346	(%, 95% CI)
ny solicited systemic reactogenicity AEs	(n, %, 95% CI) N = 2392  1129 (47.20), (45.18, 49.22) 570 (23.83) 463 (19.36) 94 (3.93) 2 (0.08)  45 (1.88), (1.38, 2.51) 31 (1.30) 11 (0.46) 3 (0.13) 0  504 (21.07), (19.45, 22.76) 212 (8.86) 251 (10.49) 41 (1.71)	340 (25.26), (22.96, 27.67)	20.75 (17.66, 23.85
Mild	570 (23.83)	204 (15.16) 48	•
Moderate	463 (19.36)	116 (8.62)	
Severe	94 (3.93)	20 (1) 49)	
Potentially Life Threatening	2 (0.08)	and o	
y y	(* /	ion ai	
ever	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) alifor	1 (0.07)	
Severe	3 (0.13)	2 (0.15)	
Potentially Life Threatening	isaci,	0	
, and the second	*HO11.	-	
Malaise Malaise	504 (21.07), (19.45, 22.76) (2	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 (171)	7 (0.52)	
Potentially Life Threatening	0	0	
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vidual group statistics are not adjusted by strata.			
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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

				3/10
		Vaccine	Placebo	Risk Difference
		(n, %, 95% CI)	(n, %, 95% CI) N = 1346	(Vaccine - Placebo)
		N = 2392	N = 1346	(%, 95% CI)
atigue	6	88 (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)	74 (1.04)	
Potentially Life Threatening		0	0 000	
			eu catio	
oint Pain	3	01 (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) 2 41011	34 (2.53)	
Severe		19 (0.79)	3 (0.22)	
Potentially Life Threatening		1 (0.04)	0	
,		ague		
Muscle Pain	6	31 (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	Wg	206 (8.61)	40 (2.97)	
Severe	" You	34 (1.42)	3 (0.22)	
Potentially Life Threatening	art ar	O ,	O ,	
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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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vavax, Inc 19nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 9.1.2_2.a Subgroup Summary of Systemic Reactogenicity Adverse Events for (>= 65 Years)			Risk Difference	
	Vaccine	Placebo	Risk Difference	
	(n, %, 95% ci) N = 2392	(n, %, 95% ci) N = 1346	(Vaccine - Placebo) (%, 95% Cl)	
leadache	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)	(0.22)		
Potentially Life Threatening	1 (0.04)	0		
g g	en	icatio.		
lausea 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) QUITO 3P	35 (2.60)	,	
Moderate	24 (1.00)	7 (0.52)		
Severe	2 (0.08)	0		
Potentially Life Threatening	0 *401	0		
	Vaccine  (n, %, 95% Cl)  N = 2392  569 (23.79), (22.09, 25.55)  434 (18.14)  116 (4.85)  18 (0.75)  1 (0.04)  126 (5.27), (4.41, 6.24)  100 (4.18)  24 (1.00) 2 (0.08) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0			
e: Risk difference and its Confidence Intervals (CIs) a	are computed from Mantel-Haenszel Standardized Risk Estima	ites and 95% normal confidence limits with th	ne stratification by study, wh	
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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)

	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Any unsolicited AEs	4627 (18.30), (17.83, 18.78)	2577 (15.68), (15.13, 16.25) 544 (3.31), (3.04, 3.60)	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) and	1.54 (1.32, 1.75)
Pyrexia	265 (1.05)	F / /// ://@// ~	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)
	emi auth	a.europa.eu 18 (0.12) 40 (0.24) 36 (0.22)	

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 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nC	oV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Even	9	Confidential 2 of 140 ose 2) by Age
Table 13.1.1.	(18-64 Y		ose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.28 (0.19, 0.37) 0.18 (0.08, 0.28)
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)	34 (0.21) 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 (0,94)	0.15 (0.08, 0.21)
Peripheral swelling	27 (0.11)	7 (0.04) 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)	euron apr 10 (0.06)	0.07 (0.01, 0.12)
	ewo	europa eu 7 (0.04) 4 (0.02) 10 (0.06)	
	ithe	), ,	

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.

# 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)

	art2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 3 of 140
Т	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Event: (18-64 Ye	-	Confidential age 3 of 140 t Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.08 (0.04, 0.12) 0.00 (-0.04, 0.05)
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 (0,91)	0.03 (0.00, 0.06)
Chest pain	10 (0.04)	19 (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)	apr 3 (0.02)	0.01 (-0.02, 0.04)
	ema.	2 (0.97) 37 2 (0.97) 37 2 (0.06) 2 (0.01) 3 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	01 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adver		Confidential ge 4 of 140  Dose 2) by Age
		(18-64 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.01, 0.05) 0.03 (-0.00, 0.06)
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)	2 (0.91) 3 (0.02)	0.02 (-0.02, 0.05)
Non-cardiac chest pain	7 (0.03)	(0.04)	0.00 (-0.04, 0.04)
Feeling hot	6 (0.02)	3 (0.02)	0.01 (-0.02, 0.04)
		ema.europa.eu 2 (0.90)  authorisation appli 6 (0.04) 3 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501  Table 13.1.1 Subgroup Summary of Unsolicited Adverse	e Events Reported from Day 0 to 49 (28 Days Post D	Confidential 5 of 140 ose 2) by Age
	(18	8-64 Years)	ariation
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.01, 0.05) 0.02 (-0.00, 0.04)
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)	ev (0.00)	0.02 (0.00, 0.05)
Vaccination site reaction	5 (0.02)	$100^{3}$ , $20/10$ (0.00)	0.02 (0.00, 0.04)
Vaccination site swelling	5 (0.02)	euro 2007 1 (<0.01)	0.02 (-0.00, 0.04)
Ç	6	ema.europa.eu (0.00) applico (0.00) 1 (<0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Magrel-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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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 Table 13 1 1 Suba		Page nts Reported from Day 0 to 49 (28 Days Post D	Confidential e 6 of 140 Occo 2) by Ago
Table 13.1.1 Subg	(18-64		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.01, 0.04) 0.02 (0.00, 0.03)
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(00.0)	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 <sub>2</sub> (<0.01)	0.01 (-0.01, 0.03)
Drug withdrawal syndrome	3 (0.01)	20/17 (<0.01)	0.00 (-0.01, 0.02)
Facial pain	3 (0.01)	eulo, 201 1 (<0.01)	0.01 (-0.01, 0.03)
	ews	a.europa.eu 7(0.01) 1 (<0.01) 2.europa.applica (<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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10 <sup>2</sup>	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adver		Confidential age 7 of 140 t Dose 2) by Age
	<b>5</b> .	(18-64 Years)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.02 (-0.00, 0.03)
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 (00.0)	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)	(0.00)	0.02 (-0.00, 0.03)
Application site pain	2 (<0.01)	(00.0)	0.01 (-0.00, 0.02)
Exercise tolerance decreased	2 (<0.01)	(0.00) 0 APP 0	0.01 (-0.00, 0.02)
		ema.europa.eu (3000)  ema.europa.applico (0.00) 0 (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019r	nCoV-301/2019nCoV-302/2019nCoV-501	Pa	Confidential ge 8 of 140
Table 13.1.	1 Subgroup Summary of Unsolicited Adverse Even (18-64 Y		Confidential ge 8 of 140 Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Illness	2 (<0.01)	1 (<0.01)	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.02, 0.02) 0.01 (-0.00, 0.02)
Injection site nodule	2 (<0.01)	0 (0.00)	0.01 (-0.00, 0.02)
Injection site papule	2 (<0.01)	0 (0.00) 1 (<0.01)	0.01 (-0.01, 0.02)
Injection site paraesthesia	2 (<0.01)	1 (<0.01) and	0.00 (-0.02, 0.02)
Injection site urticaria	2 (<0.01)		0.01 (-0.00, 0.02)
Injection site vesicles	2 (<0.01)	(0.00)	0.01 (-0.00, 0.02)
Mucosal dryness	2 (<0.01)	(<0.01)	0.00 (-0.02, 0.02)
Swelling face	2 (<0.01)	(0.00) 0 (0.00)	0.01 (-0.00, 0.02)
•	ema	europa eu (0.00) europa applica (0.00) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	01 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	· · · · · · · · · · · · · · · · · · ·	Confidential e 9 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adver	rse Events Reported from Day 0 to 49 (28 Days Post I (18-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Vaccination site inflammation	2 (<0.01)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 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 (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 (0.90)	0.01 (-0.00, 0.02)
Crepitations	1 (<0.01)	(0.00) Dhi (0.00)	0.01 (-0.00, 0.02)
Crying	1 (<0.01)	enlor 3/4 0 (0.00)	0.00 (-0.00, 0.01)
		ema europa eu 0 (0.00)  ema europa eu 0 (0.00)  0 (0.00)	

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

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adverse Ev	g .	Confidential 10 of 140 ose 2) by Age
		44 Years)	oriations original
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.02, 0.01) 0.01 (-0.00, 0.02)
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) 300	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)	20/17 (<0.01)	0.00 (-0.01, 0.01)
Local reaction	1 (<0.01)	3. EUT 3PT 0 (0.00)	0.00 (-0.00, 0.01)
	en	na.europa.eu 0 (0.96) na.europa.eu (0.00) norisation applic (0.00)	
	13.	VOI.	
	1 2018		

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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part	t2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Page	Confidential e 11 of 140
Tab	ole 13.1.1 Subgroup Summary of Unsolicited Adverse Event (18-64 Ye		Confidential 11 of 140 lose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
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)	2000, 20/10 (0.00)	0.01 (-0.00, 0.02)
Vaccination site dryness	1 (<0.01)	ento, 2 9h, 0 (0.00)	0.00 (-0.00, 0.01)
	ema.	europa, eu (0.00)  (0.00)  (158tion appli 0 (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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adverse Even		g .	Confidential e 12 of 140  Dose 2) by Age
	(18-64 )	•	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) -0.02 (-0.04, 0.01) 0.01 (-0.00, 0.02)
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 (0.00)	-0.02 (-0.04, 0.00)
Catheter site pain	0 (0.00)	2(<0.01)	-0.01 (-0.02, 0.01)
Hangover	0 (0.00)	(<0.01)	-0.01 (-0.02, 0.00)
Hernia pain	0 (0.00)	euro 2011 (<0.01)	-0.01 (-0.02, 0.01)
	ews ews	1 (<0.01)  1 (<0.01)  2 (0.02)  1 (<0.01)	

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

lovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 <b>Table 13.1.1 Subgr</b> o		nts Reported from Day 0 to 49 (28 Days Post D	Confidential 13 of 140 lose 2) by Age
	(10-01)	10013)	
_	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	زا <sup>(۱)</sup> (%, 95% CI)
Hunger	0 (0.00)	1 (<0.01)	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.00) -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) and	-0.01 (-0.02, 0.00)
Injection site pallor	0 (0.00)	1 ( 0 00)	-0.01 (-0.02, 0.00)
Injury associated with device	0 (0.00)	212(<0.01)	-0.01 (-0.02, 0.01)
Secretion discharge	0 (0.00)	100 <sup>2</sup> 1011 (<0.01)	-0.01 (-0.02, 0.00)
Systemic inflammatory response syndrome	0 (0.00)	apr 1 (<0.01)	-0.01 (-0.02, 0.00)
	-Ws	europa.eu 1 (<0.01) 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 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)

			.3/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	- (Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
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) and	-0.01 (-0.02, 0.00)
Vervous system disorders	1042 (4.12), (3.88, 4.37) 736 (2.91) 74 (0.29) 61 (0.24)	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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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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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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential 5 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse (1	e Events Reported from Day 0 to 49 (28 Days Post Dos 8-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) 0.03 (-0.03, 0.10) 0.02 (-0.05, 0.08)
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)	15 (0.09) 39 (0.24) A any	-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)	33 (0.19)	-0.09 (-0.16, -0.02)
Presyncope	15 (0.06)	2010 9 (0.05)	0.00 (-0.04, 0.05)
Hypoaesthesia	13 (0.05)	8 (0.05)	0.00 (-0.04, 0.05)
	23	14 (0.09) 21 34 (0.19) 37 (0.19) 9 (0.05) 8 (0.05)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201 Table 13	9nCoV-301/2019nCoV-302/2019nCoV-501  1.1 Subgroup Summary of Unsolicited Adverse Events		Confidential age 16 of 140 t Dose 2) by Age
ruble 13.	(18-64 Ye	-	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.03 (-0.07, 0.02) 0.00 (-0.03, 0.03) 0.01 (-0.02, 0.03)
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 (0,20)	0.02 (0.00, 0.03)
Restless legs syndrome	4 (0.02)	27(<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)	euron apr 1 (<0.01)	0.00 (-0.01, 0.02)
	ema	0 (0.00) 27 0 (0.00) 27 2 (0.01) 1 (<0.01)	
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Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/20 <sup>-</sup> Table 13	19nCoV-301/2019nCoV-302/2019nCoV-501 .1.1 Subgroup Summary of Unsolicited Adverse Events	•	Confidential ge 17 of 140 Dose 2) by Age
Table 10	(18-64 Yea	-	a riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.01, 0.03) 0.00 (-0.01, 0.02)
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)	1 (<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 (0,20)	0.01 (-0.00, 0.02)
Neuropathy peripheral	2 (<0.01)	0 (0,00)	0.01 (-0.00, 0.02)
Radiculopathy	2 (<0.01)	20/10 (0.00)	0.01 (-0.00, 0.02)
Alcoholic seizure	1 (<0.01)	501.0U gb, 0 (0.00)	0.00 (-0.00, 0.01)
	emari	Isatio	
	author	Europa en (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

ovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 13.1.1 Subgr	oup Summary of Unsolicited Adverse Ev	ents Reported from Day 0 to 49 (28 Days Post D	Confidential e 18 of 140 Pose 2) by Age
	(18-6-	4 Years)	riation.
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
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 (0,00)	0.01 (-0.00, 0.02)
Cubital tunnel syndrome	1 (<0.01)	(0.00) 0 (0.00)	0.00 (-0.00, 0.01)
Diabetic neuropathy	1 (<0.01)	60.00) 0 (0.00)	0.01 (-0.00, 0.02)
•	~~	na.europa.eu 0 (0.00) norisation applic (0.00)	
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Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501  Table 13.1.1 Subgroup Summary of Unsolicited Adverse		Confidential age 19 of 140 st Dose 2) by Age
	(18	8-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.00 (-0.01, 0.01) 0.00 (-0.00, 0.01) -0.00 (-0.01, 0.01)
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 (0 000	0.00 (-0.00, 0.01)
Migraine with aura	1 (<0.01)	0 (0.90) 5 (0.03)	-0.02 (-0.05, 0.00)
Morton's neuralgia	1 (<0.01)	20/10 (0.00)	0.01 (-0.00, 0.02)
Muscle tension dysphonia	1 (<0.01)	euro 2000)	0.01 (-0.00, 0.02)
		ema europa eu (0,00) o (0.00) o (0.00)	

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

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 20 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Even (18-64 Y		Confidential age 20 of 140 t Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Nerve compression	1 (<0.01)	1 (<0.01)	(%, 95% CI) -0.00 (-0.01, 0.01) 0.00 (-0.00, 0.01)
Peroneal nerve palsy	1 (<0.01)	0 (0.00)	0.00 (-0.00, 0.01)
Seizure anoxic	1 (<0.01)	0 (00.0)	0.01 (-0.00, 0.02)
Sleep paralysis	1 (<0.01)	0 (0.00) 300	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)	2011 (<0.01)	-0.01 (-0.02, 0.00)
Carotid artery stenosis	0 (0.00)	euro, apr 1 (<0.01)	-0.01 (-0.02, 0.01)
	ema	europa eu (5,003) europa appli (<0.01) 1 (<0.01)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 13.1.1 S	oV-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Event	-	Confidential ge 21 of 140  Dose 2) by Age
	(18-64 Ye	ears)	riations
-	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.00)
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) and	-0.01 (-0.02, 0.00)
Hemiparesis	0 (0.00)		-0.01 (-0.02, 0.00)
Hemiplegic migraine	0 (0.00)	- (-12×0.01)	-0.01 (-0.02, 0.00)
Loss of consciousness	0 (0.00)	201/Y (<0.01)	-0.01 (-0.02, 0.00)
Lumbar radiculopathy	0 (0.00)	eul (<0.01)	-0.01 (-0.02, 0.00)
	ema,	europa eu 1 (<0.01)  europa appli (<0.01)  1 (<0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

19nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/ <b>Table 13.1.1 Subgro</b> u	p Summary of Unsolicited Adverse Ev	rents Reported from Day 0 to 49 (28 Days Post D 4 Years)	Confidential 22 of 140 20se 2) by Age
	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.01)
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) and	-0.01 (-0.02, 0.01)
Musculoskeletal and connective tissue disorders	988 (3.91), (3.67, 4.15)	e360 (2.19), (1.97, 2.43)	2.50 (2.15, 2.85)
Myalgia	399 (1.58)	201102 (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)	1 (<0.01) and (0.01) and (0.01) and (0.01) and (0.01) and (0.02) (0.62) (0.62) (0.01)	0.22 (0.08, 0.36)
	14.	Voluz	

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 (2019) COV 101 Port 1, 2019 COV 1

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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nC <b>Table 13.1.1</b>	CoV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Events (18-64 Yea	Reported from Day 0 to 49 (28 Days Post	Confidential ge 23 of 140 Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class Preferred Term (# of Subjects)	(n, %, 95% CI) N = 25282	(n, %, 95% CI) N = 16433	(Vaccine - Placebo) (%, 95% CI)
Back pain Musculoskeletal stiffness	68 (0.27) 22 (0.09)	51 (0.31) 9 (0.05)	(%, 95% CI) 0.00 (-0.11, 0.11) 0.06 (-0.00, 0.11)
Neck pain Muscle spasms	19 (0.08) 15 (0.06)	9 (0.05) 22 (0.13) 13 (0.08) and any	-0.02 (-0.07, 0.04)
Osteoarthritis Tendonitis	12 (0.05) 9 (0.04)	3 (0.02) 3 (0.01)	0.03 (-0.01, 0.06) 0.02 (-0.01, 0.05)
Rotator cuff syndrome Limb discomfort	8 (0.03) 7 (0.03)	3 (0.02) 3 (0.01) 3 (0.02) 5 (0.03)	0.02 (-0.01, 0.05) 0.01 (-0.02, 0.05)
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	a sutri		

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13.1.1 S</b> t	oV-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Event: (18-64 Ye	s Reported from Day 0 to 49 (28 Days Post	Confidential ge 24 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class Preferred Term (# of Subjects)	(n, %, 95% CI) N = 25282	(n, %, 95% CI) N = 16433	(Vaccine - Placebo) (%, 95% CI)
Joint swelling Musculoskeletal chest pain Musculoskeletal pain Pain in jaw Bursitis Arthritis Costochondritis Limb mass	6 (0.02) 6 (0.02) 6 (0.02) 6 (0.02) 5 (0.02) 4 (0.02) 4 (0.02) 4 (0.02)	5 (0.03) 8 (0.05) 1 (<0.01) 0 (0.00) 7 (0.01) 7 (0.01) 3 (0.02) 2 (0.01)	(Vaccine - Placebo) (%, 95% Cl)  -0.00 (-0.03, 0.03) -0.02 (-0.06, 0.02) 0.02 (-0.01, 0.04) 0.02 (0.00, 0.04) -0.03 (-0.06, 0.01) -0.00 (-0.02, 0.02) -0.00 (-0.03, 0.03) 0.01 (-0.01, 0.04)
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Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo		9	Confidential ge 25 of 140
Table 13.1.1 St	ubgroup Summary of Unsolicited Adverse Eveni (18-64 Y		Confidential ge 25 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.00 (-0.02, 0.02) 0.01 (-0.00, 0.03)
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) and	0.01 (-0.01, 0.03)
Intervertebral disc protrusion	3 (0.01)		-0.01 (-0.04, 0.02)
Joint stiffness	3 (0.01)	ev (0.00)	0.01 (-0.00, 0.03)
Muscle swelling	3 (0.01)	(00.00)	0.01 (-0.00, 0.03)
Axillary mass	2 (<0.01)	5 (0.03)	-0.02 (-0.04, 0.01)
·	ews	europa en 3 (0.00) europa applico (0.00) 5 (0.03)	
	autho	), ·	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCc		-	Confidential ge 26 of 140
Table 13.1.1 S	ubgroup Summary of Unsolicited Adverse Eve (18-64	nts Reported from Day 0 to 49 (28 Days Post Years)	Confidential ge 26 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.02, 0.02) 0.00 (-0.02, 0.02)
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)	1 (<0.01) @(0.00)	0.00 (-0.00, 0.01)
Fibromyalgia	1 (<0.01)	(<0.01)	-0.00 (-0.01, 0.01)
Joint effusion	1 (<0.01)	euro, apr 0 (0.00)	0.00 (-0.00, 0.01)
	EW	a.europa.eu (<0.00) a.europa.applici(<0.01) 0 (0.00)	
	auth	O'	

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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	01 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	•	Confidential 27 of 140 ose 2) by Age
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse (1)	8-64 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.00 (-0.00, 0.01) 0.01 (-0.00, 0.02)
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 (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)	eV (0.00)	0.01 (-0.00, 0.02)
Neck mass	1 (<0.01)	(<0.01)	0.00 (-0.01, 0.01)
Nodal osteoarthritis	1 (<0.01)	0 (0.00)	0.01 (-0.00, 0.02)
	3)	uthorisation application of (0.00)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events	g	Confidential 28 of 140 ose 2) by Age
	(18-64 Yea	ars)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) -0.00 (-0.02, 0.01)
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)	(00.0) (00.0)	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)	(0.00)	0.01 (-0.00, 0.02)
Spinal osteoarthritis	1 (<0.01)	20/0 (0.00)	0.00 (-0.00, 0.01)
Synovial cyst	1 (<0.01)	1 (<0.01)	-0.00 (-0.02, 0.01)
	ema.	o (0.00) Suropa appli 6 (0.00) 1 (<0.01)	

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

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 <b>Table 13.1.1 Subg</b>	roup Summary of Unsolicited Adverse Eve	nts Reported from Day 0 to 49 (28 Days Post I Years)	Confidential e 29 of 140  Cose 2) by Age
	·	,	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.01 (-0.00, 0.02)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
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 (00.0)	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)	2 ( 0.01)	-0.01 (-0.02, 0.00)
Medial tibial stress syndrome	0 (0.00)	(<0.01)	-0.01 (-0.02, 0.01)
Muscle discomfort	0 (0.00)	2 (0.01)	-0.01 (-0.02, 0.00)
	emi	0 (0.00) 1 (<0.01) 1 (<0.01) 2 (0.01) 2 (0.01)	<b>,</b> , ,

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.

Table 13.1.1 S	Subgroup Summary of Unsolicited Adverse Event (18-64 Yo	ts Reported from Day 0 to 49 (28 Days Post D	Confidential e 30 of 140 e 30 ose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Myalgia intercostal	0 (0.00)	1 (<0.01)	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.00) -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 (<0.00)	-0.01 (-0.02, 0.01)
Torticollis	0 (0.00)	Opa.eu nicato.01)	-0.01 (-0.02, 0.00)
Infections and infestations	666 (2.63), (2.44, 2.84)	2500 (3.04), (2.79, 3.32)	-0.28 (-0.61, 0.06)
Upper respiratory tract infection	96 (0.38) ema	1 (<0.01) and 1 (<0.01) and 1 (<0.01) and 200 (3.01) 200 (3.04), (2.79, 3.32) 51 (0.31)	0.09 (-0.02, 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 (2019pCoV 101 Port 1, 2019-20 V 104 Po

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Page	Confidential e 31 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Ev (18-6	ents Reported from Day 0 to 49 (28 Days Post I 4 Years)	Confidential e 31 of 140 Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Urinary tract infection	58 (0.23)	43 (0.26)	(Vaccine - Placebo) (%, 95% Cl) -0.03 (-0.12, 0.07) -0.12 (-0.21, -0.02)
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) and	-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)	2011 (11 (0.07)	0.01 (-0.04, 0.06)
Tonsillitis	18 (0.07)	7 (0.04)	0.04 (-0.00, 0.09)
	ent	24 (0.15) 21 24 (0.15) 21 21 (0.15) 21 21 (0.15) 21 21 (0.15) 21 21 (0.15) 21 21 (0.12) 21 21 (0.15) 21 21 (0	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13.1.1 S</b>	ubgroup Summary of Unsolicited Adverse Event	ts Reported from Day 0 to 49 (28 Days Post E	Confidential e 32 of 140 Dose 2) by Age
	(18-64 Yo	ears)	oriatio,
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% Cl) 0.02 (-0.03, 0.07) -0.00 (-0.05, 0.04)
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)
	ews	11 (0.07) 11 (0.07) 12 (0.09) 24 (0.15) 4 (0.02)	
	a auti.		

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

9nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 13.1.1 Subgr		Pag hts Reported from Day 0 to 49 (28 Days Post	e 33 of 140 Dose 2) by Age
•	(18-64 )		ariations
_	Vaccine	Placebo	Risk Difference
rstem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.04 (0.00, 0.07) 0.01 (-0.02, 0.05)
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)	4 (0.02) 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 (0,92)	0.02 (-0.02, 0.05)
Cystitis	8 (0.03)	4 (0.92) 12(0.01)	0.03 (0.00, 0.06)
Lower respiratory tract infection	8 (0.03)	2000 2011 (0.07)	-0.02 (-0.06, 0.03)
Pneumonia	7 (0.03)	europa eu (0.02) 11 (0.07) 2 (0.01)	0.01 (-0.02, 0.04)
	am <sub>s</sub>	i. ation	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nC Table 13.1.1 \$	oV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Even	· ·	Confidential e 34 of 140 Dose 2) by Age
	(18-64 \		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.02, 0.03) 0.01 (-0.02, 0.04)
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) 5 (0.03) 5 (0.03)	-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)
	ema	4 (0.02) 4 (0.02) 5 (0.03) 9 (0.05)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Report (18-64 Years)		Confidential age 35 of 140 t Dose 2) by Age
Vaccine	Placebo	Risk Difference
(n, %, 95% CI) N = 25282	(n, %, 95% Cl) N = 16433	(Vaccine - Placebo) (%, 95% CI)
5 (0.02) 4 (0.02) 4 (0.02) 4 (0.02) 4 (0.02) 4 (0.02) 4 (0.02) 4 (0.02)	5 (0.03) 1 (<0.01) and any	(Vaccine - Placebo) (%, 95% CI) -0.02 (-0.05, 0.01) -0.01 (-0.03, 0.02) -0.01 (-0.05, 0.02) 0.01 (-0.01, 0.03) -0.01 (-0.01, 0.03) 0.01 (-0.01, 0.03) 0.01 (-0.01, 0.03)
	Vaccine (18-64 Ye  Vaccine (n, %, 95% Cl) N = 25282  5 (0.02) 4 (0.02) 4 (0.02) 4 (0.02)	Vaccine Placebo (n, %, 95% Cl) (n, %, 95% Cl) N = 25282 N = 16433  5 (0.02) 4 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13.1.1 Su</b>	ubgroup Summary of Unsolicited Adverse Event	s Reported from Day 0 to 49 (28 Days Post I	Confidential e 36 of 140 Dose 2) by Age
	(18-64 Ye	ears)	ariatio.
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.00 (-0.02, 0.03) 0.01 (0.00, 0.03)
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) any	-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 (9.01)	0.00 (-0.02, 0.02)
Laryngitis	3 (0.01)	(<0.01)	0.01 (-0.01, 0.03)
Localised infection	3 (0.01)	en, o (0.00)	0.01 (-0.00, 0.02)
	ema	europa eu (0.01) europa appli (<0.01) 0 (0.00)	
	itho	(1-	
	a au		

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

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Re (18-64 Years)	ported from Day 0 to 49 (28 Days Post I	Confidential e 37 of 140 Dose 2) by Age
_	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.04, 0.02) -0.01 (-0.03, 0.02) 0.01 (-0.00, 0.03)
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)	(00.0) (00.0)	0.01 (-0.00, 0.03)
Subcutaneous abscess	3 (0.01)	1 (<0.01) and	0.01 (-0.01, 0.02)
Tinea pedis	3 (0.01)		0.01 (-0.00, 0.03)
Viral pharyngitis	3 (0.01)	(*0.01)	0.00 (-0.01, 0.02)
Abscess	2 (<0.01)	OPO 2011 0 (0.00)	0.01 (-0.00, 0.02)
Candida infection	2 (<0.01)	1 (<0.01)	0.00 (-0.01, 0.02)
	3 (0.01) 3 (0.01) 2 (<0.01) 2 (<0.01) ema.eu	itio.	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	01 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adver		Confidential 38 of 140 use 2) by Age
		(18-64 Years)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.01, 0.02) 0.01 (-0.00, 0.02)
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) and	0.00 (-0.01, 0.02)
Labyrinthitis	2 (<0.01)	2 (0.0%)	-0.01 (-0.03, 0.02)
Osteomyelitis	2 (<0.01)	3 (0.92)	0.01 (-0.00, 0.02)
Post procedural infection	2 (<0.01)	20Pic 2011 0 (0.00)	0.01 (-0.00, 0.02)
Rash pustular	2 (<0.01)	euro (0.00)	0.01 (-0.00, 0.02)
		ema.europa.eu 3 (0.00)  ema.europa.eu (0.00) 0 (0.00)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential age 39 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse (18	Events Reported from Day 0 to 49 (28 Days Pos 8-64 Years)	Confidential age 39 of 140 at Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
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)	e (0.00)	0.00 (-0.00, 0.01)
Bed bug infestation	1 (<0.01)	$200^{20}$ $2010^{-0}$ (0.00)	0.01 (-0.00, 0.02)
Body tinea	1 (<0.01)	euro 2 apr 1 (<0.01)	-0.00 (-0.02, 0.01)
·	e al	europa europa (0.00)  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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 40 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse E (18-6	vents Reported from Day 0 to 49 (28 Days Post 64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Chromoblastomycosis	1 (<0.01)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
Chronic sinusitis	1 (<0.01)	0 (0.00)	0.00 (-0.00, 0.01)
Dysentery	1 (<0.01)	(00.0) (00.0) 0	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)	0 (0.90) 212 (0.01)	-0.00 (-0.01, 0.01)
Empyema	1 (<0.01)	(0.00) 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)
	er	na.europa.eu 0 (0,00) horisation applic (0,00)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501  Table 13.1.1 Subgroup Summary of Unsolicited Adverse	9	Confidential le 41 of 140  Dose 2) by Age
	<b>5</b> .	8-64 Years)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
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)	eV (0.00)	0.00 (-0.00, 0.01)
Herpes zoster reactivation	1 (<0.01)	(0.00) ap/10 (0.00)	0.00 (-0.00, 0.01)
Impetigo	1 (<0.01)	2 (<0.01)	-0.00 (-0.01, 0.01)
	3	ema.europa.eu 1 (<0.00)  1 (<0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-101 Table 13.1.1	CoV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Events		Confidential age 42 of 140 t Dose 2) by Age
	(18-64 Ye		riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) -0.00 (-0.01, 0.01) 0.01 (-0.00, 0.02)
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 (00.0)	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)	1 (<0.07)	0.00 (-0.00, 0.01)
Oral fungal infection	1 (<0.01)	(0.00) ap/10 (0.00)	0.00 (-0.00, 0.01)
Oropharyngeal gonococcal infection	1 (<0.01)	eulo, 26, 0 (0.00)	0.01 (-0.00, 0.02)
	ema.	europa.eu (30.00) o (0.00)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Par	t2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Page	Confidential e 43 of 140
Та	ble 13.1.1 Subgroup Summary of Unsolicited Adverse Event (18-64 Yo		Confidential e 43 of 140 Pose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Pericoronitis	1 (<0.01)	0 (0.00)	(%, 95% CI) 0.00 (-0.00, 0.01) 0.01 (-0.00, 0.02)
Pharyngeal abscess	1 (<0.01)	0 (0.00)	0.01 (-0.00, 0.02)
Pharyngitis bacterial	1 (<0.01)	0 (00.0)	0.01 (-0.00, 0.02)
Pilonidal cyst	1 (<0.01)	1 (<0.01) and	-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)	(0.00)	0.01 (-0.00, 0.02)
Pulpitis dental	1 (<0.01)	(<0.01)	-0.00 (-0.02, 0.01)
Respiratory tract infection	1 (<0.01)	euro 2010 (0.00)	0.00 (-0.00, 0.01)
	ema	europa eu 0 (0.00) europa applic (<0.01) 0 (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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019	nCoV-301/2019nCoV-302/2019nCoV-501	Pa	Confidential ge 44 of 140
Table 13.1.	.1 Subgroup Summary of Unsolicited Adverse Events R (18-64 Year		Confidential ge 44 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Respiratory tract infection viral	1 (<0.01)	2 (0.01)	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.01) 0.00 (-0.00, 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 (0 000 0	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)	(<0.01)	-0.00 (-0.01, 0.01)
Urethritis	1 (<0.01)	0(0.00)	0.01 (-0.00, 0.02)
	ema.e	uropa en (0.00) applic (0.01) 0 (0.00)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Par	rt2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Pag	Confidential te 45 of 140
Та	ble 13.1.1 Subgroup Summary of Unsolicited Adverse Events Re (18-64 Years)		Confidential e 45 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
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 (0 000 0	0.01 (-0.00, 0.02)
Viral labyrinthitis	1 (<0.01)	0 (0.00)	0.01 (-0.00, 0.02)
Vulvitis	1 (<0.01)	1000 april 0 (0.00)	0.00 (-0.00, 0.01)
Abscess neck	0 (0.00) ويا	1 (<0.01)	-0.01 (-0.02, 0.00)
	1 (<0.01) 1 (<0.01) 1 (<0.01) 0 (0.00) ema.eu	ation.	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/20			Confidential ge 46 of 140
Table 1	3.1.1 Subgroup Summary of Unsolicited Adverse Event (18-64 Yo		Confidential ge 46 of 140 : Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.01)
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)	27(<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)	eulto, 24, 1 (<0.01)	-0.01 (-0.02, 0.01)
	ema	europa eu 1 (<0.01) europa appli (2 (0.01) 1 (<0.01)	

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

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo\ <b>Table 13.1.1 Su</b>	bgroup Summary of Unsolicited Adverse Eve	Pagents Reported from Day 0 to 49 (28 Days Post • Years)	Confidential ge 47 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
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) 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)	4 ( 0.00) ()	-0.01 (-0.02, 0.00)
Genital abscess	0 (0.00)	ev (12(×0.01)	-0.01 (-0.02, 0.00)
Genitourinary chlamydia infection	0 (0.00)	(0.01) (×0.01)	-0.01 (-0.02, 0.01)
Gingivitis	0 (0.00)	4 (0.02)	-0.02 (-0.04, -0.00)
	em	a.europa.eu 1 (<0.01) a.europa.appli (<0.01) 4 (0.02)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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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2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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)

		.2/10
Vaccine	Placebo	Risk Difference
(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
N = 25282	N = 16433	(%, 95% CI)
0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.01)
0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.00)
	1 any	
0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.01)
0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.00)
0 (0.00)	(20.01)	-0.01 (-0.02, 0.00)
0 (0.00)	200 2011 (<0.01)	-0.01 (-0.02, 0.01)
0 (0.00)	eulo, apr 1 (<0.01)	-0.01 (-0.02, 0.01)
0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.01)
	er, risa	
	itho,	
2 2	100	
ring		
	(n, %, 95% CI) N = 25282 0 (0.00) 0 (0.00) 0 (0.00)	(n, %, 95% CI) N = 25282 N = 16433 0 (0.00) 1 (<0.01) 0 (0.00) 1 (<0.01) 0 (0.00) 1 (<0.01) 0 (0.00) 1 (<0.01) 0 (0.00) 0 (0.00) 1 (<0.01) 0 (0.00) 1 (<0.01) 0 (0.00) 1 (<0.01) 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.

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

# 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)

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Tabl</b> e <b>13.1.1 S</b> i	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Ever	9	Confidential the 49 of 140  Dose 2) by Age
	(18-64)	Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
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) 1 (<0.01)	-0.01 (-0.02, 0.01)
Pelvic inflammatory disease	0 (0.00)	1 (<0.01) and	-0.01 (-0.02, 0.01)
Perichondritis	0 (0.00)		-0.01 (-0.02, 0.00)
Periorbital cellulitis	0 (0.00)	2 (×0.01)	-0.01 (-0.02, 0.00)
Pyelonephritis	0 (0.00)	2011 (<0.01)	-0.01 (-0.02, 0.01)
Pyelonephritis acute	0 (0.00)	eulo 2 apr 1 (<0.01)	-0.01 (-0.02, 0.01)
	e me	reuropa eu 1 (<0.01) 1. europa applit (<0.01) 1. (<0.01) 1. (<0.01)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13.1.1 S</b>	Pa Bond Policited Adverse Events Reported from Day 0 to 49 (28 Days Post (18-64 Years)		Confidential age 50 of 140 t Dose 2) by Age
System Organ Class	Vaccine (n, %, 95% CI)	Placebo (n, %, 95% Cl)	Risk Difference (Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
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) and	-0.01 (-0.02, 0.01)
Syphilis	0 (0.00)		-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)	$20^{10}$	-0.02 (-0.03, 0.00)
Viral sinusitis	0 (0.00)	1 (3001) 1 (3001) 1 (3002) 1 (<0.01) 1 (<0.01)	-0.01 (-0.02, 0.01)
	a auth	10113	

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 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)

			.2/10
	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Viral tonsillitis	0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.00)
Wound infection	0 (0.00)	1 (<0.01)	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.00)
		4 SUL	
astrointestinal 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)	05 (0.50)	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)
	e,	risa	
	ithe	),	
	a all		
	156 (0.62) 144 (0.57) 53 (0.21) 31 (0.12) 26 (0.10) ema		
	1/6		

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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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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-		9	Confidential e 52 of 140
Table 13.1.1 Sub	group summary of Unsolicited Adverse Even (18-64 )	its Reported from Day 0 to 49 (28 Days Post l (ears)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Gastrooesophageal reflux disease	25 (0.10)	16 (0.10)	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.05, 0.07) 0.04 (-0.01, 0.09) -0.02 (-0.08, 0.03)
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)	(0.02)	0.02 (-0.01, 0.05)
Food poisoning	7 (0.03)	$200^{23}$ $20/13$ (0.02)	0.01 (-0.02, 0.04)
Dry mouth	6 (0.02)	euro 2011 1 (<0.01)	0.02 (-0.00, 0.05)
	ELUS	2 (0.01) 27 2 (0.01) 27 2 (0.02) 3 (0.02) 1 (<0.01)	
	autho	D., .	

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

# 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)

	rart2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Fable 13.1.1 Subgroup Summary of Unsolicited Adverse Even (18-64 N	its Reported from Day 0 to 49 (28 Days Post Do	Confidential 53 of 140 ose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.03, 0.03) -0.00 (-0.03, 0.03)
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)	2 EU (8 (0.00)	0.01 (-0.00, 0.03)
Faeces soft	3 (0.01)	20/0 (0.00)	0.01 (-0.00, 0.02)
Flatulence	3 (0.01)	euro, 364 0 (0.00)	0.01 (-0.00, 0.03)
	eme	europa eu 2 (0.00) 1. europa appli 6 (0.00) 0 (0.00)	

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

# 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)

	/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential age 54 of 140
Table	e 13.1.1 Subgroup Summary of Unsolicited Adverse Events Ro (18-64 Years		Confidential age 54 of 140 at Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Gingival recession	3 (0.01)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.01, 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 (<0.07)	0.01 (-0.01, 0.02)
Stomatitis	3 (0.01)	(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)
	3 (0.01) 3 (0.01) 3 (0.01) 2 (<0.01) ema.eu	ation,	

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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Page	Confidential 55 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse (18-	Events Reported from Day 0 to 49 (28 Days Post Do -64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.01 (-0.00, 0.02)
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)	0 (0.00) 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)	1 (<0.01) 2 (0.00)	0.00 (-0.00, 0.01)
Aphthous ulcer	1 (<0.01)	$200^{10}$ $200^{10}$	-0.01 (-0.03, 0.01)
Ascites	1 (<0.01)	0(0.00)	0.00 (-0.00, 0.01)
	e' av	ma.europa.eu (2(0.00) o (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3			Confidential age 56 of 140
lable 13.1.1 Subg	-	events Reported from Day 0 to 49 (28 Days Pos 64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Cannabinoid hyperemesis syndrome	1 (<0.01)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.01 (-0.00, 0.02)
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)	2011 (<0.01)	-0.00 (-0.02, 0.02)
Duodenogastric reflux	1 (<0.01)	3. EUT 3P 0 (0.00)	0.00 (-0.00, 0.01)
	el	thorisation applications of (0.00)	
	aut	Chia.	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

ovavax, Inc 19nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 13.1.1 Subar		Paç nts Reported from Day 0 to 49 (28 Days Post	Confidential ge 57 of 140  Dose 2) by Age
•	•	Years)	
	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.03, 0.01) 0.01 (-0.00, 0.02)
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)	(00.0) (00.0)	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)	eV (20.01)	-0.00 (-0.02, 0.01)
Impaired gastric emptying	1 (<0.01)	(<0.01)	-0.00 (-0.02, 0.01)
Intestinal obstruction	1 (<0.01)	0 (0.00)	0.00 (-0.00, 0.01)
	em	0 (0.00) and 1 (0.01) (0.00) application application of (0.00)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	· · · · · · · · · · · · · · · · · · ·	Confidential 58 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Ev (18-6	vents Reported from Day 0 to 49 (28 Days Post Do 64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Lip blister	1 (<0.01)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
Loose tooth	1 (<0.01)	0(0.0)	0.00 (-0.00, 0.01)
Mouth cyst	1 (<0.01)	0 (0.00) 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)		0.00 (-0.00, 0.01)
Oral blood blister	1 (<0.01)	0 (0.00)	0.01 (-0.00, 0.02)
Oral disorder	1 (<0.01)	(0.00) 0 // CO	0.00 (-0.00, 0.01)
Pancreatitis	1 (<0.01)	eulo, 3Pr 1 (<0.01)	-0.00 (-0.02, 0.01)
	en's	na europa eu (0.00) na europa applicó (0.00) 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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV Table 13.1.1 Su	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Event	9	Confidential e 59 of 140 Dose 2) by Age
	(18-64 Ye	ears)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.00 (-0.02, 0.02) -0.00 (-0.02, 0.01)
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)	1 (<0.01) 0 (0.00)	0.01 (-0.00, 0.02)
Salivary gland enlargement	1 (<0.01)	1 (<0.01) and	0.00 (-0.01, 0.01)
Swollen tongue	1 (<0.01)		0.00 (-0.00, 0.01)
Tooth loss	1 (<0.01)	e (0.00)	0.00 (-0.00, 0.01)
Umbilical hernia	1 (<0.01)	20P2 2011 0 (0.00)	0.00 (-0.00, 0.01)
Uvulitis	1 (<0.01)	6/1/2 3h, 0 (0.00)	0.00 (-0.00, 0.01)
	ews	europa eu 0 (0.00) europa appli 6 (0.00) o (0.00)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10 <sup>.</sup>	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	9	Confidential e 60 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Ev (18-64	ents Reported from Day 0 to 49 (28 Days Post D 4 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) -0.01 (-0.02, 0.01)
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) 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)	100° 2011 (<0.01)	-0.01 (-0.02, 0.01)
Gastritis erosive	0 (0.00)	euro 2 2PF 1 (<0.01)	-0.01 (-0.02, 0.00)
	em	1 (<0.01) 1 (<0.01) 1 (<0.01) 1 (<0.01) 1 (<0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

# 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)

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV- <b>Table 13.1.1 Sub</b>		nts Reported from Day 0 to 49 (28 Days Post	Confidential ge 61 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.00)
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) 2 (0.01)	-0.01 (-0.02, 0.01)
Hiatus hernia	0 (0.00)	e <sup>()</sup> (2)(0.01)	-0.01 (-0.03, 0.00)
Hyperaesthesia teeth	0 (0.00)	(<0.01)	-0.01 (-0.02, 0.01)
Hypoaesthesia oral	0 (0.00)	euro, 3Pr 1 (<0.01)	-0.01 (-0.02, 0.00)
	emi	a europa en 1 (<0.01)  a europa applic (<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.

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			3/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	- (Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.03, 0.00) -0.01 (-0.02, 0.01)
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)  1 (<0.01)  1 (<0.01)  2897 (2.42), (2.19, 2.66)  120 (0.73)	-0.01 (-0.02, 0.01)
Respiratory, thoracic and mediastinal disorders	494 (1.95), (1.79, 2.13)	2897 (2.42), (2.19, 2.66)	-0.18 (-0.48, 0.11)
Oropharyngeal pain	135 (0.53)	na : sation 120 (0.73)	-0.05 (-0.20, 0.11)
	, and the second	horis	
	all		
	ating		

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).

	2019nCoV-301/2019nCoV-302/2019nCoV-501	•	Confidential ge 63 of 140
Table <sup>1</sup>	13.1.1 Subgroup Summary of Unsolicited Adverse Events F (18-64 Year	•	Confidential ge 63 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.08 (-0.23, 0.07) -0.14 (-0.29, 0.01)
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) and	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)	1000° 2011 (0.07)	-0.01 (-0.06, 0.03)
Throat irritation	11 (0.04)	4 (0.02)	0.02 (-0.01, 0.06)
	ema.s	12 (0.07) 37 12 (0.07) 12 (0.07) 11 (0.07) 4 (0.02)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201			Confidential ge 64 of 140
Table 13.	1.1 Subgroup Summary of Unsolicited Adverse Event (18-64 Y		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.04, 0.04) 0.02 (-0.02, 0.05)
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)	3 (0.02) 5 (0.03)	0.01 (-0.02, 0.05)
Paranasal sinus discomfort	6 (0.02)	1 (<0.01) and	0.02 (-0.01, 0.04)
Dry throat	5 (0.02)		-0.00 (-0.03, 0.03)
Sinus pain	5 (0.02)	2 (9.01)	0.01 (-0.01, 0.04)
Pharyngeal erythema	4 (0.02)	20/10 (0.00)	0.01 (0.00, 0.03)
Dysphonia	3 (0.01)	eul (<0.01)	0.01 (-0.01, 0.03)
	ema autho	europa eu 5 (0.03) europa applico (0.00) 1 (<0.01)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 <b>Table 13.1.1 Subg</b> r		nts Reported from Day 0 to 49 (28 Days Post I	Confidential e 65 of 140  Dose 2) by Age
Contain One of Class	Vaccine (5.0% OF)	Placebo	Risk Difference
System Organ Class Preferred Term (# of Subjects)	(n, %, 95% Cl) N = 25282	(n, %, 95% CI) N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) -0.01 (-0.04, 0.02)
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) and	-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)	euro 2 2 (<0.01)	0.00 (-0.01, 0.02)
-	emi	1 (<0.01) and 5 (0.03) 14(0.01) 2 (0.01) 1 (<0.01) 0 risation	

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

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	-	Confidential ge 66 of 140  Dose 2) by Age
'	Fable 13.1.1 Subgroup Summary of Unsolicited Adverse Ev (18-6)	4 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.02, 0.02) 0.00 (-0.01, 0.02)
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 (00.0)	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)	(0.00)	0.00 (-0.00, 0.01)
Nasal mucosal ulcer	1 (<0.01)	00.00)	0.01 (-0.00, 0.02)
Nasal polyps	1 (<0.01)	(0.00) 0 apr	0.00 (-0.00, 0.01)
. •	em	1 (<0.01) and 0 (0.00) and 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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019n Table 13 1 1	CoV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Events	•	Confidential ge 67 of 140  Dose 2) by Age
Table 13.1.1	(18-64 Yea		buse 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) -0.01 (-0.03, 0.01)
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)	(00.0) (00.1)	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)	200 2011 (<0.01)	0.00 (-0.01, 0.01)
Pulmonary pain	1 (<0.01)	0 (0.00)	0.01 (-0.00, 0.02)
	ema.e	uropa eu (0.00) appli (0.00) o (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

# 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)

	rt2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 68 of 140
	ble 13.1.1 Subgroup Summary of Unsolicited Adverse Eveni (18-64 Y	•	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Reflux laryngitis	1 (<0.01)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) -0.01 (-0.02, 0.01)
Respiratory tract congestion	1 (<0.01)	2 (0.01)	-0.01 (-0.02, 0.01)
Rhinalgia	1 (<0.01)	0(00.0)	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)	eV (0.00)	0.00 (-0.00, 0.01)
Throat tightness	1 (<0.01)	20/17 (<0.01)	-0.00 (-0.02, 0.01)
Tonsillar inflammation	1 (<0.01)	EULOU 3D1 0 (0.00)	0.01 (-0.00, 0.02)
	ema utho	europa eu 0 (0.00)  Relicon applic (<0.01)  0 (0.00)	

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

	019nCoV-301/2019nCoV-302/2019nCoV-501 3.1.1 Subgroup Summary of Unsolicited Adverse Events	`	Confidential ge 69 of 140  Dose 3) by Age
Table I	(18-64 Yea		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) 0.00 (-0.01, 0.01) -0.01 (-0.02, 0.00)
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)	12(<0.01)	-0.01 (-0.02, 0.01)
Nasal discomfort	0 (0.00)	1000 20/17 (<0.01)	-0.01 (-0.02, 0.00)
Nasal disorder	0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.00)
	ema. ema. e	1 (<0.01) 2 (<0.01) 2 (<0.01) 1 (<0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

Table 13.1.1 St	oV-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Events F (18-64 Year	Reported from Day 0 to 49 (28 Days Post E	Confidential e 70 of 140 Pose 2) by Age
	Vaccine	Placebo	Risk Difference
stem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
referred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.02 (-0.03, 0.00) -0.01 (-0.02, 0.00)
leuritic pain	0 (0.00)	3 (0.02)	-0.02 (-0.03, 0.00)
espiratory symptom	0 (0.00)	2 (0.01)	-0.01 (-0.02, 0.00)
inonasal obstruction	0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.00)
onsillar hypertrophy	0 (0.00)	1 (<0.01) and	-0.01 (-0.02, 0.00)
n and subcutaneous tissue disorders	316 (1.25), (1.12, 1.39)	e 165 (1,00), (0.86, 1.17)	0.36 (0.15, 0.56)
ash	78 (0.31)	200 a 0 (0.24)	0.07 (-0.03, 0.18)
ruritus	46 (0.18)	13 (0.08)	0.13 (0.06, 0.20)
Irticaria	24 (0.09)	1 (<0.01) and (0.01) and (0.01) and (0.01) and (0.02) (0.00) (0.00) (0.00) (0.00) (0.00) (0.00) (0.00) (0.00) (0.00) (0.00)	0.05 (0.00, 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 (2019) COV 101 Port 1, 2019, CV 1

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019n			Confidential ge 71 of 140
Table 13.1.1	Subgroup Summary of Unsolicited Adverse Events (18-64 Yea		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Erythema	23 (0.09)	6 (0.04)	(Vaccine - Placebo) (%, 95% CI) 0.06 (0.01, 0.11) 0.04 (-0.00, 0.08)
Dermatitis contact	17 (0.07)	4 (0.02)	0.04 (-0.00, 0.08)
Hyperhidrosis	16 (0.06)	4 (0.02) 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)	, (0 0 m O	0.01 (-0.03, 0.05)
Cold sweat	8 (0.03)	6 (0.04) 2 (0.01)	0.03 (-0.00, 0.06)
Dermatitis	8 (0.03)	2011 8 (0.05)	-0.01 (-0.05, 0.03)
Night sweats	7 (0.03)	4 (0.02)	0.01 (-0.02, 0.04)
	ema.e	6 (0.04) (0.01) 8 (0.05) 4 (0.02)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCc Table 13 1 1 S	oV-301/2019nCoV-302/2019nCoV-501  ubgroup Summary of Unsolicited Adverse Ever	g	Confidential 72 of 140 ose 2) by Age
Table 13.1.13	(18-64)		ariations s
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.02 (0.00, 0.04) -0.00 (-0.04, 0.03)
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)	eV (2)(0.01)	0.01 (-0.01, 0.04)
Rash erythematous	4 (0.02)	$700^{3}$	-0.02 (-0.06, 0.01)
Skin lesion	4 (0.02)	3 (0.02)	-0.00 (-0.03, 0.03)
	EM	1 (<0.01) and 12 (0.07) 12 (0.07) 2 (0.01) 7 (0.04) 3 (0.02)	
	auth'	J.	

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.

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nC		9	Confidential e 73 of 140
Table 13.1.1 S	Subgroup Summary of Unsolicited Adverse Eve (18-64	nts Reported from Day 0 to 49 (28 Days Post E Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Alopecia	3 (0.01)	2 (0.01)	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.02, 0.02) 0.01 (-0.01, 0.03)
Dry skin	3 (0.01)	1 (<0.01)	0.01 (-0.01, 0.03)
Ingrowing nail	3 (0.01)	1 (<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)	(9.02)	-0.01 (-0.04, 0.01)
Pityriasis rosea	2 (<0.01)	2 (0.01)	-0.00 (-0.02, 0.02)
Psoriasis	2 (<0.01)	3 EULO 1 364 0 (0.00)	0.01 (-0.00, 0.02)
	ELL	2 (0.01) 3 (0.02) 3 (0.02) 3 (0.02) 2 (0.01) 0 (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	11 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	•	Confidential 74 of 140 use 2) by Age
	Table 13.1.1 Subgroup Summary of Unsolicited Advers (1	e Events Reported Holli Day 0 to 49 (26 Days Post Do 18-64 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	
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 (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 (0 000 0	0.00 (-0.00, 0.01)
Dermatitis acneiform	1 (<0.01)	6 (0.00)	0.01 (-0.00, 0.02)
Dermatosis	1 (<0.01)	DD 2011 0 (0.00)	0.00 (-0.00, 0.01)
Diffuse alopecia	1 (<0.01)	0 (0.00)	0.00 (-0.00, 0.01)
		ema, europa, eu (0,00) ema, europa, applicó (0.00) o (0.00)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 13.1.1 Su	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Event	9	Confidential 75 of 140 ose 2) by Age
	(18-64 Ye		oriations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
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 (0,90)	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)	(<0.01)	-0.00 (-0.01, 0.01)
Pemphigoid	1 (<0.01)	en o (0.00)	0.01 (-0.00, 0.02)
	ews.	europa eu (0.00)  europa appli (<0.01) 0 (0.00)	

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

	t2/2019nCoV-301/2019nCoV-302/2019nCoV-501	•	Confidential ge 76 of 140
Tal	ble 13.1.1 Subgroup Summary of Unsolicited Adverse Events (18-64 Yea		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
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)	0 (0.00) 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)	20/10 (0.00)	0.01 (-0.00, 0.02)
Skin hyperpigmentation	1 (<0.01)	0 (0.00)	0.00 (-0.00, 0.01)
	ema.	Europa en (0.00) Europa applico (0.00) 0 (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.

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019			Confidential age 77 of 140 t Dose 2) by Age
Table 13.1	1.1 Subgroup Summary of Unsolicited Adverse Event (18-64 Ye		
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01) -0.01 (-0.02, 0.01)
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) and	-0.01 (-0.02, 0.00)
Hand dermatitis	0 (0.00)		-0.01 (-0.02, 0.00)
Hidradenitis	0 (0.00)	2 (0.01)	-0.01 (-0.02, 0.01)
Keratolysis exfoliativa acquired	0 (0.00)	(<0.01)	-0.01 (-0.02, 0.00)
Macule	0 (0.00)	euron apr 1 (<0.01)	-0.01 (-0.02, 0.01)
	ema	risation	
	autho	europa, eu (2(0.01) (<0.01) (<0.01) (isation appli (<0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 20:16

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo	oV-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Evel	•	ge 78 of 140
Table 13.1.1 3	(18-64		Confidential ge 78 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.01)
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) 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) 3 (0.02)	-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)	200 20/17 (<0.01)	-0.01 (-0.02, 0.00)
Skin exfoliation	0 (0.00)	eulo 2 2 (<0.01)	-0.01 (-0.02, 0.00)
	eme	1 (<0.01) 3.europa.eu (<0.01) 3.europa.appli( (<0.01) 1 (<0.01) 0 risation	

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 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)

Table 13.1.1 Subgro	up Summary of Unsolicited Adverse Event (18-64 Ye	s Reported from Day 0 to 49 (28 Days Post I ears)	Confidential e 79 of 140 Dose 2) by Age
_	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Skin mass	0 (0.00)	1 (<0.01)	Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.00) -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) and	-0.02 (-0.05, -0.00)
njury, poisoning and procedural complications	249 (0.98), (0.87, 1.11)	e)58 (0.96), (0.82, 1.12)	0.05 (-0.15, 0.25)
Contusion	23 (0.09)	(0.05)	0.05 (-0.01, 0.10)
Skin laceration	19 (0.08)	all (0.07)	0.01 (-0.05, 0.06)
Muscle strain	15 (0.06) ema	4 (0.02) and (0.02) and (0.05) (0.82, 1.12) (0.05) (0.07) (0.07) (0.04)	0.01 (-0.03, 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 (2019pCoV 101 Port 1, 2019-20 V 104 Po

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 13.1.1 Su		Pa ents Reported from Day 0 to 49 (28 Days Posi	Confidential age 80 of 140 t Dose 2) by Age
	• •	4 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.00, 0.07) -0.03 (-0.09, 0.02)
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)	(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)	3.euron apr 0 (0.00)	0.02 (0.00, 0.04)
	em	9 (0.05) 4 (0.02) 4 (0.02) 4 (0.02) 0 (0.00)	
	151.	70,	

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. 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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2	2019nCoV-301/2019nCoV-302/2019nCoV-501	Pag	Confidential ge 81 of 140
Table '	13.1.1 Subgroup Summary of Unsolicited Adverse Events (18-64 Ye		Confidential ge 81 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.03, 0.03) 0.01 (-0.01, 0.04)
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 (0.00)	2 (2 20)	-0.00 (-0.03, 0.02)
Concussion	4 (0.02)	3 (0,02) 3 (0.02)	-0.01 (-0.03, 0.02)
Meniscus injury	4 (0.02)	$200^{2}$	-0.00 (-0.02, 0.02)
Thermal burn	4 (0.02)	5 (0.03)	-0.01 (-0.04, 0.02)
	ema.	3 (0.02) 3 (0.02) 2 (0.01) 5 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	I Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	9	Confidential e 82 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse (18	Events Reported from Day 0 to 49 (28 Days Post E 3-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Arthropod bite	3 (0.01)	3 (0.02)	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.03, 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)	3 (0.02) 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)	4 (0.02) 2 (0.01)	0.01 (-0.02, 0.03)
Wound	3 (0.01)	20/10 (0.00)	0.01 (-0.00, 0.02)
Alcohol poisoning	2 (<0.01)	all (<0.01)	-0.00 (-0.02, 0.02)
	e al'	4 (0.02) 4 (0.02) (0.00) 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.

	:/2019nCoV-301/2019nCoV-302/2019nCoV-501 e 13.1.1 Subgroup Summary of Unsolicited Adverse Events		Confidential age 83 of 140 t Dose 2) by Age
	(18-64 Ye		riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.01 (-0.00, 0.02)
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)	(0.00)	0.01 (-0.00, 0.02)
Nerve injury	2 (<0.01)	2000, $2010$ , $2000$	0.01 (-0.00, 0.02)
Post procedural fever	2 (<0.01)	O(0.00)	0.01 (-0.00, 0.02)
	ema	europa.eu 2(0,00) europa.appli 0 (0.00) 0 (0.00)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	9	Confidential ge 84 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Advers	se Events Reported from Day 0 to 49 (28 Days Post (18-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.01 (-0.00, 0.02)
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)	ev (0.00)	0.01 (-0.00, 0.02)
Procedural vomiting	2 (<0.01)	(0.00) ap/10 (0.00)	0.01 (-0.00, 0.02)
Radius fracture	2 (<0.01)	2 (0.01)	-0.01 (-0.03, 0.01)
		ema.europa.eu 3 (0.00)  ema.europa.applico (0.00) 2 (0.01)	
		authic	

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

	/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 85 of 140
Table	13.1.1 Subgroup Summary of Unsolicited Adverse Events (18-64 Ye		Confidential ge 85 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) -0.00 (-0.02, 0.02)
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)	1 (<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)	22(0.01)	-0.00 (-0.02, 0.02)
Accidental overdose	1 (<0.01)	2010 (0.00)	0.00 (-0.00, 0.01)
Bone contusion	1 (<0.01)	2 (0.01)	-0.01 (-0.03, 0.01)
	erna.	Europa, eu 2 (0.01)  Europa applico (0.00) 2 (0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 20:16

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3		Pa vents Reported from Day 0 to 49 (28 Days Post	Confidential ge 86 of 140 Dose 2) by Age
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	· · · · · · · · · · · · · · · · · · ·	64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
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 (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 (0.00)	0.01 (-0.00, 0.02)
Exposure to communicable disease	1 (<0.01)	(0.00)	0.00 (-0.00, 0.01)
Eyelid abrasion	1 (<0.01)	2000 (0.00)	0.00 (-0.00, 0.01)
Femur fracture	1 (<0.01)	na.europa.eu 0 (0.00) na.europa.eu 0 (0.00) norisation applic 0 (0.00)	0.01 (-0.00, 0.02)
	en	narisatio	

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

	2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential age 87 of 140
Tab	le 13.1.1 Subgroup Summary of Unsolicited Adverse Events (18-64 Yea		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) -0.02 (-0.04, 0.01) 0.00 (-0.00, 0.01)
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)	0 (0.00) 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)	-1a (0.01)	-0.00 (-0.02, 0.01)
Incision site pain	1 (<0.01)	2000 ap/10 (0.00)	0.00 (-0.00, 0.01)
Intentional overdose	1 (<0.01)	0(0.00)	0.01 (-0.00, 0.02)
	erna.	Europa, eu (0,00) (0,00) 0 (0.00) 0 (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 12 1 1 S	oV-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Even	· · · · · · · · · · · · · · · · · · ·	Confidential e 88 of 140 Pose 3) by Age
Table 13.1.1 3	(18-64 Y		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
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 (0.00)	0.01 (-0.00, 0.02)
Musculoskeletal injury	1 (<0.01)	1 (<0.01) and	-0.00 (-0.02, 0.01)
Overdose	1 (<0.01)		-0.01 (-0.03, 0.01)
Post procedural discomfort	1 (<0.01)	e (0.00)	0.01 (-0.00, 0.02)
Post procedural haematoma	1 (<0.01)	2000.000	0.00 (-0.00, 0.01)
Post procedural pruritus	1 (<0.01)	en o (0.00)	0.00 (-0.00, 0.01)
	ewg	europa eu 2 (0.00) Drisation appli (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13 1 1 S</b> i		Page nts Reported from Day 0 to 49 (28 Days Post D	Confidential e 89 of 140 lose 2) by Age
Tuble 13.1.1 36	(18-64		ariations o
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) 0.00 (-0.01, 0.01) -0.01 (-0.02, 0.01)
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)	2 (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)	(0.00) 0 (0.00)	0.01 (-0.00, 0.02)
Tendon injury	1 (<0.01)	2 (0.01)	-0.01 (-0.02, 0.01)
	e <sub>LU</sub> ,	Reuropa en (0,00) 3. europa applica (0.01) 2 (0.01) 2 (0.01)	
	ith	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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	9	Confidential ge 90 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Education (18-6)	vents Reported from Day 0 to 49 (28 Days Post 64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.03, 0.01) 0.00 (-0.00, 0.01)
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)	(00.0) (00.0)	0.00 (-0.00, 0.01)
Eye contusion	0 (0.00)	1 (<0.01) 200	-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)	e (1,0001)	-0.01 (-0.02, 0.00)
Foreign body in ear	0 (0.00)	(<0.01)	-0.01 (-0.02, 0.00)
Injury	0 (0.00)	2 (<0.01)	-0.01 (-0.02, 0.01)
	en	1 (<0.01) and 3 (0.02) and 3 (0.02) and (<0.01) 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.

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

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential 91 of 140
	- · · · · · · · · · · · · · · · · · · ·	rse Events Reported from Day 0 to 49 (28 Days Post Do (18-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	
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)	ev (10×0.01)	-0.01 (-0.02, 0.00)
Procedural hypertension	0 (0.00)	200 <sup>2</sup> 2011 (<0.01)	-0.01 (-0.02, 0.00)
Scar	0 (0.00)	2 (<0.01)	-0.01 (-0.02, 0.00)
		ema.europa.eu 1 (<0.01)  ema.europa.appli (<0.01) 1 (<0.01) authorisation appli (<0.01)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019n <b>Table 13.1.1</b>	CoV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Events (18-64 Yea	Reported from Day 0 to 49 (28 Days Post De	Confidential 92 of 140 ose 2) by Age
-	Vaccine	Placebo	Risk Difference
System Organ Class Preferred Term (# of Subjects)	(n, %, 95% CI) N = 25282	(n, %, 95% CI) N = 16433	(Vaccine - Placebo) (%, 95% CI)
Spinal column injury Toxicity to various agents Traumatic arthritis Wound dehiscence	0 (0.00) 0 (0.00) 0 (0.00) 0 (0.00)	1 (<0.01) 1 (<0.01) 1 (<0.01) 1 (<0.01)	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
Psychiatric disorders Anxiety Depression Insomnia	147 (0.58), (0.49, 0.68) 44 (0.17) 28 (0.11) 24 (0.09) ema.	280 (0.49) (0.39, 0.61) 27 (0.16) 16 (0.10) 14 (0.09)	0.10 (-0.04, 0.25) 0.01 (-0.07, 0.09) 0.01 (-0.05, 0.08) 0.02 (-0.04, 0.08)
	ating author	190	

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 (2019) COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019 COV 101

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

ovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 13.1.1 Subgro		Page ents Reported from Day 0 to 49 (28 Days Post E	Confidential e 93 of 140  Oose 2) by Age
	(18-64	Years)	
_	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.02 (-0.06, 0.02) 0.02 (-0.01, 0.04)
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)	eV	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)	euro, 364 0 (0.00)	0.01 (-0.00, 0.02)
	am	1 (<0.01) at (<0.01) at (<0.01) at (<0.01) at (<0.01) at (<0.01) at (<0.02) at (<0.02) at (<0.00) a	
		orise	

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

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	`	Confidential ge 94 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Ev (18-6	vents Reported from Day 0 to 49 (28 Days Post 64 Years)	Confidential ge 94 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) 0.01 (-0.01, 0.02) 0.00 (-0.00, 0.01)
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)	(12×0.01)	-0.00 (-0.01, 0.01)
Confusional state	1 (<0.01)	20/10 (0.00)	0.00 (-0.00, 0.01)
Delirium tremens	1 (<0.01)	60.00) 0 (0.00)	0.01 (-0.00, 0.02)
	en aut	1 (<0.01) 31 (<0.01) 31 (<0.01) 1 (<0.01) 31 (<0.01) (0.00) (0.00) 0 (0.00) (0.00)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	9	Confidential 95 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Ev (18-6-	ents Reported from Day 0 to 49 (28 Days Post Do 4 Years)	Confidential 95 of 140 ose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Dependence	1 (<0.01)	0 (0.00)	(%, 95% CI) 0.00 (-0.00, 0.01) -0.00 (-0.02, 0.02)
Depressive symptom	1 (<0.01)	1 (<0.01)	-0.00 (-0.02, 0.02)
Disorientation	1 (<0.01)	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 (<0.07)	-0.00 (-0.02, 0.02)
Hallucination	1 (<0.01)	(0.00)	0.00 (-0.00, 0.01)
Homicidal ideation	1 (<0.01)	2010 (0.00)	0.00 (-0.00, 0.01)
Hypervigilance	1 (<0.01)	(0.00) apr 0	0.00 (-0.00, 0.01)
	ent	1 (3001) 10 (0.00) 10 (0.00) 10 (0.00)	

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

Jovavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 13.1.1 Subgro		Pagonts Reported from Day 0 to 49 (28 Days Post I	Confidential e 96 of 140  Pose 2) by Age
i dalio i o i i i o daligi c	(18-64		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.01 (-0.00, 0.02)
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)	1 (<0.01)	0.00 (-0.00, 0.01)
Obsessive-compulsive disorder	1 (<0.01)	$200^{20}$ , $2010^{10}$ (0.00)	0.00 (-0.00, 0.01)
Restlessness	1 (<0.01)	enlow 3h, 0 (0.00)	0.01 (-0.00, 0.02)
	emi	a.europa.eu (3000) orisation applico (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13.1.1 S</b> u	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Even (18-64 Y	ts Reported from Day 0 to 49 (28 Days Post	Confidential ge 97 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.01 (-0.00, 0.02)
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 (0.00)	0.00 (-0.00, 0.01)
Agitation	0 (0.00)	2 (0.01)	-0.01 (-0.03, 0.00)
Alcoholism	2 (2 22)	1 ( 0 00) (	-0.01 (-0.02, 0.01)
Hypomania	0 (0.00)	2 (×0.01)	-0.01 (-0.02, 0.00)
Libido decreased	0 (0.00)	1000 - 2011 (<0.01)	-0.01 (-0.02, 0.01)
Mental disorder	0 (0.00)	europa eu (2001) europa appli (20.01) 1 (20.01)	-0.01 (-0.02, 0.01)
	ELLIC	risatio	
	autho	),	

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. 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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_sub.sas\_18JUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			3/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	- (Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.00)
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)
		1 SUL	
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)
	er, or	1500	
	"tho"		
	alle		
	102 (0.40) 7 (0.03) 7 (0.03) 7 (0.03) 6 (0.02)  **Reting author		
	, Ke		

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2			Confidential ge 99 of 140
Table 1	3.1.1 Subgroup Summary of Unsolicited Adverse Event (18-64 Y		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.01 (-0.01, 0.02) 0.01 (-0.00, 0.02)
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) 300	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)	(0.00)	0.01 (-0.00, 0.02)
Arteriosclerosis	1 (<0.01)	(0.00) 0 (0.00)	0.00 (-0.00, 0.01)
Diastolic hypertension	1 (<0.01)	(0.00) apr 0	0.00 (-0.00, 0.01)
<del></del>	ema	europa en (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.

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 <b>Table 13.1.1 Sub</b> ç	group Summary of Unsolicited Adverse Ever (18-64 )	nts Reported from Day 0 to 49 (28 Days Post	Confidential ge 100 of 140 t Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
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 (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)	(0.00)	0.00 (-0.00, 0.01)
Phlebitis	0 (0.00)	(<0.01)	-0.01 (-0.02, 0.01)
Systolic hypertension	0 (0.00)	reuropa eu (0.00) reuropa applic (<0.01) 1 (<0.01)	-0.01 (-0.02, 0.00)
	emo	:catio	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV		9	Confidential 101 of 140
Table 13.1.1 Su	bgroup Summary of Unsolicited Adverse Events (18-64 Yea	•	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.23 (0.09, 0.36) 0.18 (0.06, 0.30)
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)	2 (0 030 0	0.00 (-0.02, 0.03)
Lymphadenitis	3 (0.01)	(12(×0.01)	0.01 (-0.01, 0.02)
Anaemia vitamin B12 deficiency	1 (<0.01)	(0.00) 0 (0.00)	0.00 (-0.00, 0.01)
Blood loss anaemia	1 (<0.01)	0 (0.00)	0.00 (-0.00, 0.01)
	ema.e	Juropa eu 3 (0.02) Juropa appli 0 (0.00) 0 (0.00)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019n Table 13.1.1	CoV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Events (18-64 Yea	Page 1 Reported from Day 0 to 49 (28 Days Post Do	Confidential 102 of 140 use 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01) -0.01 (-0.03, 0.01)
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 (<0.07)	-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)	Uro 24 (0.15)	0.01 (-0.06, 0.08)
Respiratory rate increased	0 (0.00) 122 (0.48), (0.40, 0.58) 31 (0.12) 15 (0.06)  ema.e	sation 20 (0.12)	-0.03 (-0.09, 0.03)
	eting auc.		

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 (2019) COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019 COV 101

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 Table 13.1.1 Subg	roup Summary of Unsolicited Adverse Ev	ents Reported from Day 0 to 49 (28 Days Post 4 Years)	Confidential e 103 of 140  Dose 2) by Age
	`		
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Body temperature increased	14 (0.06)	3 (0.02)	(Vaccine - Placebo) (%, 95% CI) 0.04 (0.01, 0.08) -0.03 (-0.08, 0.01)
SARS-CoV-2 test positive	10 (0.04)	10 (0.06)	-0.03 (-0.08, 0.01)
Heart rate increased	8 (0.03)	10 (0.06) 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 (0.02)	0.01 (-0.01, 0.04)
Blood pressure systolic increased	4 (0.02)	eV (0.01)	0.01 (-0.02, 0.03)
Prostatic specific antigen increased	3 (0.01)	(0.00) DONO (0.00)	0.01 (-0.00, 0.03)
Blood cholesterol increased	2 (<0.01)	3 (0.02)	-0.01 (-0.04, 0.02)
	en	Taleuropa eu 2 (0.801)  1.a.europa applico (0.00)  3 (0.02)	, ,

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

ovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 <b>Table 13.1.1 Subg</b>	roup Summary of Unsolicited Adverse Eve	ents Reported from Day 0 to 49 (28 Days Post D	Confidential 104 of 140 lose 2) by Age
	(18-64	Years)	riation
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.01 (-0.00, 0.02)
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)	(00.0) 0	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 (0,21)	-0.01 (-0.02, 0.01)
Blood phosphorus decreased	1 (<0.01)	(0.00)	0.00 (-0.00, 0.01)
Blood testosterone decreased	1 (<0.01)	20(0.00)	0.00 (-0.00, 0.01)
Blood triglycerides increased	1 (<0.01)	60.00) 0 (0.00)	0.00 (-0.00, 0.01)
	m.	a.europa.eu 2(0.90) a.europa.appli (0.00) 0 (0.00)	
	SI.	risa	

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

ovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 <b>Table 13.1.1 Subgro</b>	oup Summary of Unsolicited Adverse Eve	ents Reported from Day 0 to 49 (28 Days Post D	Confidential e 105 of 140  Oose 2) by Age
	(18-64	1 Years)	riation
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.01, 0.01)
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)	(0.00)	0.00 (-0.00, 0.01)
Heart rate decreased	1 (<0.01)	2000000000000000000000000000000000000	0.01 (-0.00, 0.02)
Heart rate irregular	1 (<0.01)	O(0.00)	0.01 (-0.00, 0.02)
	-17	a.europa.eu 0 (0.00) a.europa.appli 0 (0.00) 0 (0.00)	
	SI.	risa	

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

ovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 <sup>°</sup> <b>Table 13.1.1 Subgr</b> o	oup Summary of Unsolicited Adverse E	Pag Events Reported from Day 0 to 49 (28 Days Post I 64 Years)	Confidential e 106 of 140  Dose 2) by Age
	·	,	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
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)	(0.00)	0.01 (-0.00, 0.02)
Blood creatinine increased	0 (0.00)	$200^{3}$	-0.01 (-0.03, 0.00)
Blood potassium decreased	0 (0.00)	2010 1 (<0.01)	-0.01 (-0.02, 0.01)
	0.5	na europa eu (0.00) ha europa applica (0.01) thorisation applica (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.

# 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)

vavax, Inc 19nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported fro (18-64 Years)		nts Reported from Day 0 to 49 (28 Days Post Do	Confidential 107 of 140 ose 2) by Age
	(10-04)	i eai sj	ariatio
	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.00)
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)	ev	-0.01 (-0.02, 0.00)
Occult blood positive	0 (0.00)	100° 20/17 (<0.01)	-0.01 (-0.02, 0.00)
SARS-CoV-2 test	0 (0.00)	euro 2011 (<0.01)	-0.01 (-0.02, 0.01)
	w <sub>s</sub>	europa eu (3001) leuropa appli (3001) 1 (<0.01)	
	SI.	risa	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			3/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Weight increased	0 (0.00)	3 (0.02)	(Vaccine - Placebo) (%, 95% CI) -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)
	23 (0.09)	14 (0.00)	•
Decreased appetite	10 (0.07)	14 (0.09) and	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)	(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)
	EI,	1500	
	itho,		
	18 (0.07) 9 (0.04) 6 (0.02) 5 (0.02) 4 (0.02) ema.		
	ating		
	1/6		

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 (2019 p.Ca.V. 101 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 103 Part 1, 20

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCc 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)

	/2019nCoV-301/2019nCoV-302/2019nCoV-501 13.1.1 Subgroup Summary of Unsolicited Adverse Events	•	Confidential e 109 of 140  Dose 2) by Age
Таме	(18-64 Yea		
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.02 (-0.05, 0.01) -0.01 (-0.03, 0.02)
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)	1 (<0.01) 2 (0.01)	-0.01 (-0.03, 0.01)
Diabetic ketoacidosis	1 (<0.01)	100 (0.00)	0.00 (-0.00, 0.01)
Electrolyte imbalance	1 (<0.01)	0(0.00)	0.00 (-0.00, 0.01)
	ema.	Europa eu (2001) Europa appli (2001) (0.00) (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Page 1	Confidential 10 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse (1	e Events Reported from Day 0 to 49 (28 Days Post Dos 18-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Hypoferritinaemia	1 (<0.01)	0 (0.00)	Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) -0.02 (-0.05, 0.00)
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)	200° 2011 2 (0.01)	-0.01 (-0.03, 0.01)
Hyperglycaemia	0 (0.00)	3 (0.02)	-0.02 (-0.04, 0.00)
		0 (0.00) 0 (0.00) 0 (0.00) 2 (0.01) 3 (0.02) 0 (0.00) 2 (0.01) 3 (0.02)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			3/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
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)
		, 3U.	
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)		0.04 (0.01, 0.06)
Photophobia	8 (0.03)	(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)
	6/,	<i>i</i> 1500	
	1,th <sup>0</sup>	, ·	
	alle		
	8 (0.03) 8 (0.03) 6 (0.02) 6 (0.02) 5 (0.02) ema		

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 (2019 p.Ca.V. 101 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 103 Part 1, 20

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).

# 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)

	t2/2019nCoV-301/2019nCoV-302/2019nCoV-501	•	Confidential ge 112 of 140
Tac	ole 13.1.1 Subgroup Summary of Unsolicited Adverse Events (18-64 Ye		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Swelling of eyelid	4 (0.02)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.01 (0.00, 0.03) -0.00 (-0.02, 0.02)
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)	2010 (0.00)	0.01 (-0.00, 0.03)
Diplopia	2 (<0.01)	0(0.00)	0.01 (-0.00, 0.02)
	erna.	europa.eu 0 (0.00) europa.applico (0.00) 0 (0.00)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019n Toble 13.1.1			ge 113 of 140
Table 13.1.1	I Subgroup Summary of Unsolicited Adverse Ever (18-64)		Confidential ge 113 of 140 t Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) -0.02 (-0.05, 0.01) 0.00 (-0.01, 0.02)
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)	1 (<0.01) 0 (0.00)	0.01 (-0.00, 0.02)
Uveitis	2 (<0.01)	1 (<0.01) and	-0.00 (-0.02, 0.02)
Vision blurred	2 (<0.01)		-0.00 (-0.02, 0.02)
Vitreous detachment	2 (<0.01)	€ <sup>(1)</sup> (₹(0.01)	-0.00 (-0.02, 0.02)
Vitreous floaters	2 (<0.01)	2000, $2010$ , $2000$	0.01 (-0.00, 0.02)
Chalazion	1 (<0.01)	0(0.00)	0.00 (-0.00, 0.01)
	ema	Jeuropa eu 2 (0.00) Jeuropa applicó (0.00) Orisation applicó (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 114 of 140
1	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Eve (18-64	ents Reported from Day 0 to 49 (28 Days Post Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
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 (0.00)	0.00 (-0.00, 0.01)
Eye irritation	1 (<0.01)	2 (0.01) 300	-0.01 (-0.03, 0.01)
Iridocyclitis	1 (<0.01)	0 (0,00)	0.00 (-0.00, 0.01)
Iritis	1 (<0.01)	e ( 20.01)	-0.00 (-0.02, 0.01)
Keratitis	1 (<0.01)	(0.00) 0 (0.00)	0.00 (-0.00, 0.01)
Macular oedema	1 (<0.01)	0(0.00)	0.00 (-0.00, 0.01)
	emi	2 (0.01) and 0 (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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV	/-301/2019nCoV-302/2019nCoV-501 bgroup Summary of Unsolicited Adverse Even		Confidential e 115 of 140  Posse 3) by Age
Table 13.1.1 Su	(18-64 Y		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
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)	0 (0.00) 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)	0 (0,00) 3 (0.02)	-0.02 (-0.03, 0.00)
Corneal oedema	0 (0.00)	(<0.01)	-0.01 (-0.02, 0.01)
Dacryostenosis acquired	0 (0.00)	euro 2 (0.01)	-0.01 (-0.02, 0.00)
	EWS	europa eu (0.00) 1. europa applica (0.02) 2 (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)

			3/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
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)	ev12(×0.01)	-0.01 (-0.02, 0.01)
Retinal tear	0 (0.00)	Uropa applit (<0.01)	-0.01 (-0.02, 0.00)
Reproductive system and breast disorders	73 (0.29), (0.23, 0.36)	1 (<0.01) 12 (<0.01) 10 (<0.01) 10 (<0.01) 10 (0.24), (0.17, 0.32) 14 (0.24)	0.06 (-0.04, 0.16)
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	ing au		

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo		9	Confidential ge 117 of 140
Table 13.1.1 St	• •	nts Reported from Day 0 to 49 (28 Days Post Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.02, 0.06) 0.02 (-0.00, 0.04)
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)	eV (2.01)	0.00 (-0.02, 0.02)
Menstrual disorder	3 (0.01)	$200^{20}$ , $2010^{2}$ (0.00)	0.01 (-0.00, 0.03)
Ovarian cyst	3 (0.01)	3 EUTO 1 3PV 0 (0.00)	0.01 (-0.00, 0.02)
	EW	a.europa.eu 2(0.00) a.europa.appli 6 (0.00) 0 (0.00)	
	outh out	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.

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adver-	· · · · · · · · · · · · · · · · · · ·	Confidential 118 of 140 ose 2) by Age
		(18-64 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.00 (-0.02, 0.02) 0.01 (-0.00, 0.02)
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)	27 (20.01)	0.00 (-0.01, 0.02)
Balanoposthitis	1 (<0.01)	20/10 (0.00)	0.00 (-0.00, 0.01)
Bartholin's cyst	1 (<0.01)	euro 20 (0.00)	0.01 (-0.00, 0.02)
		ema.europa.eu 3(0,927) appli 0 (0.00) ema.europa.appli 0 (0.00)	

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

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 119 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Advers	se Events Reported from Day 0 to 49 (28 Days Post (18-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) -0.00 (-0.02, 0.01)
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)	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)	(0.00)	0.00 (-0.00, 0.01)
Menometrorrhagia	1 (<0.01)	2000000000000000000000000000000000000	0.01 (-0.00, 0.02)
Metrorrhagia	1 (<0.01)	eulo 2 apr 1 (<0.01)	-0.00 (-0.01, 0.01)
		ema europa eu 1 (<0.00)  ema risation appli 6 (0.00)  1 (<0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	•	Confidential ge 120 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse (1	e Events Reported from Day 0 to 49 (28 Days Post 8-64 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Nipple pain	1 (<0.01)	0 (0.00)	(Vaccine - Placebo) (%, 95% Cl) 0.00 (-0.00, 0.01) 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 (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 (0 000	0.00 (-0.00, 0.01)
Scrotal swelling	1 (<0.01)	e (0.00)	0.00 (-0.00, 0.01)
Testicular cyst	1 (<0.01)	2010 (0.00)	0.01 (-0.00, 0.02)
Testis discomfort	1 (<0.01)	0(0.00)	0.01 (-0.00, 0.02)
	3	ema.europa.eu 0 (0.00)  o (0.00)  o (0.00)  o (0.00)	

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

# 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)

	t2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential age 121 of 140
lat	ole 13.1.1 Subgroup Summary of Unsolicited Adverse Events (18-64 Yea		Confidential age 121 of 140 t Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.00 (-0.00, 0.01) -0.02 (-0.04, 0.01)
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)	3 (0.02) 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)	(20.01)	-0.01 (-0.02, 0.01)
Menopausal symptoms	0 (0.00)	2011 (<0.01)	-0.01 (-0.02, 0.00)
Polycystic ovaries	0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.01)
	ema.	Europa en 2 (0.01) Europa appli (<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.

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			aric
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	- (Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.01)
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) 2 (0.01)	-0.01 (-0.02, 0.00)
Uterine cyst	0 (0.00)	eV (2(0.01)	-0.01 (-0.03, 0.00)
Uterine pain	0 (0.00)	1100pa, 3pp//4 (<0.01)	-0.01 (-0.02, 0.01)
Ear and labyrinth disorders	65 (0.26), (0.20, 0.33)	1 (3001) 1 (3001) 3 (0.01) 3 (0.01) 3 (0.01) 3 (0.01) 3 (0.01)	0.07 (-0.02, 0.16)
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	ating acc		

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo 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)

	2019nCoV-301/2019nCoV-302/2019nCoV-501	-	Confidential ge 123 of 140  Dose 2) by Age
lable	13.1.1 Subgroup Summary of Unsolicited Adverse Events R (18-64 Year		. (2)
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.02, 0.07) 0.01 (-0.04, 0.05)
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)	7 (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)	2 (2 20%)	0.01 (-0.02, 0.03)
Ear canal erythema	2 (<0.01)	21 (×0.01)	-0.00 (-0.02, 0.02)
Ear congestion	2 (<0.01)	0000 0000	0.01 (-0.00, 0.02)
Eustachian tube dysfunction	2 (<0.01)	0(0.00)	0.01 (-0.00, 0.02)
,	emale	uropa.eu 3 (0.00) 0 (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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adve	•	Confidential e 124 of 140  Dose 2) by Age
		(18-64 Years)	ariations o
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.02, 0.01) 0.00 (-0.00, 0.01)
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)	(0.00)	0.01 (-0.00, 0.02)
Middle ear effusion	1 (<0.01)	(0.00) 0 (0.00)	0.00 (-0.00, 0.01)
Paraesthesia ear	1 (<0.01)	enless 3/4 0 (0.00)	0.00 (-0.00, 0.01)
		ema.europa.eu 0 (0.00)  ema.europa.eu 0 (0.00) 0 (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).

# 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)

119nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Tabl</b> e <b>13.1.1 S</b> i	ubgroup Summary of Unsolicited Adverse Events (18-64 Ye	Reported from Day 0 to 49 (28 Days Post D	Confidential 125 of 140 ose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Tympanic membrane perforation	1 (<0.01)	1 (<0.01)	-0.00 (-0.01, 0.01)
Otorrhoea	0 (0.00)	2 (0.01)	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.01, 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 (0.92)	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)	27 (0.16), (0.11, 0.24) 4 (0.02) 4 (0.05) 2 (0.01) 2 (0.01) 0 (0.00)	0.01 (-0.00, 0.02)
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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).

# 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)

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Page erse Events Reported from Day 0 to 49 (28 Days Post Do	Confidential 126 of 140 ose 2) by Age
	Table 13.1.1 Subgroup Summary of Offsonicited Adve	(18-64 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) 0.00 (-0.02, 0.02) -0.01 (-0.04, 0.01)
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)	eV12(×0.01)	-0.00 (-0.02, 0.01)
Atrioventricular block complete	1 (<0.01)	2000 $2010$ $(0.00)$	0.01 (-0.00, 0.02)
Atrioventricular block first degree	1 (<0.01)	O(0.00)	0.00 (-0.00, 0.01)
		ema.europa.eu 0 (0.00)  ema.europa.eu 0 (0.00) 0 (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.

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	01 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.1 Subgroup Summary of Unsolicited Adver	•	Confidential e 127 of 140 Pose 2) by Age
		(18-64 Years)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
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 (00.0)	0.00 (-0.00, 0.01)
Myocardial infarction	1 (<0.01)	0 (0.00) 200	0.00 (-0.00, 0.01)
Myocarditis	1 (<0.01)	0 (0,90)	0.01 (-0.00, 0.02)
Sinus tachycardia	1 (<0.01)	0 (0,00) 0 (0,00)	0.00 (-0.00, 0.01)
Stress cardiomyopathy	1 (<0.01)	ODO ODIO (0.00)	0.00 (-0.00, 0.01)
Supraventricular extrasystoles	1 (<0.01)	29. Europ apr 0 (0.00)	0.00 (-0.00, 0.01)
		ema.europa.eu 0 (0.00)  ema.europa.eu 0 (0.00)  o (0.00)	

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

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			.3/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.01 (-0.00, 0.02)
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) and	-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) and 1 (<0.01) 1 (<0.01) 2 europa eu nica (0.01) 3 europa eu nica (0.01) 5 (0.03, 0.12) 5 (0.03)	-0.01 (-0.02, 0.01)
mmune system disorders	38 (0.15), (0.11, 0.21)	211 (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)
	-h'	oris	
	auli		
	ating		
	.// 6		

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 (2019 p.Ca.V. 101 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 103 Part 1, 20

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).

# 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)

	t2/2019nCoV-301/2019nCoV-302/2019nCoV-501 ble 13.1.1 Subgroup Summary of Unsolicited Adverse Event	•	Confidential ge 129 of 140  Dose 2) by Age
	(18-64 Yo	ears)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.00, 0.05) 0.03 (0.01, 0.05)
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) and	0.01 (-0.01, 0.02)
Allergic reaction to excipient	1 (<0.01)	0 (0,90)	0.00 (-0.00, 0.01)
Allergy to arthropod bite	1 (<0.01)	(0.00)	0.01 (-0.00, 0.02)
Allergy to chemicals	1 (<0.01)	(0.00) Dhi (0.00)	0.00 (-0.00, 0.01)
Allergy to metals	1 (<0.01)	O(0.00)	0.01 (-0.00, 0.02)
	ema	europa eu 0 (0.00)  europa applico (0.00)  0 (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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 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)

			3/10
	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.00) -0.01 (-0.02, 0.00)
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)
		7 31/11	
enal 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)	4 ( 0 00) 0	0.02 (-0.00, 0.04)
Nephrolithiasis	6 (0.02)	(0.02)	-0.01 (-0.04, 0.02)
Haematuria	4 (0.02)	(0.00) 0 (0.00)	0.02 (0.00, 0.03)
Incontinence	2 (<0.01)	O(0.00)	0.01 (-0.00, 0.02)
Acute kidney injury	1 (<0.01)	1 (<0.01)	-0.00 (-0.02, 0.01)
	6/,	risas	
	14/hC	),	
	alle		
	6 (0.02) 6 (0.02) 4 (0.02) 2 (<0.01) 1 (<0.01) ema		
	VI 60		

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 (2019 p.Ca.V. 101 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 103 Part 1, 20

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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019r	nCoV-301/2019nCoV-302/2019nCoV-501 1 Subgroup Summary of Unsolicited Adverse Eve		Confidential age 131 of 140
Table 15.1.	(18-64		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.00, 0.02) 0.01 (-0.00, 0.02)
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)	0 (0.00) 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 (0,90)	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)	(<0.01)	-0.01 (-0.02, 0.01)
Costovertebral angle tenderness	0 (0.00)	eulo, 201 (<0.01)	-0.01 (-0.02, 0.00)
	em <sup>r</sup> auth	a.europa.eu (0,000) 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.

# 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)

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 132 of 140
	Table 13.1.1 Subgroup Summary of Unsolicited Adverse Event (18-64 Ye	-	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
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) 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 (<0.00)	-0.01 (-0.02, 0.01)
Renal pain	0 (0.00)	-1a(<0.01)	-0.01 (-0.02, 0.00)
Urethral dilatation	0 (0.00)	(<0.01)	-0.01 (-0.02, 0.00)
Urinary retention	0 (0.00)	apr 1 (<0.01)	-0.01 (-0.02, 0.00)
·	ema,	1 (<0.01) and 1 (<0.01) and 1 (<0.01) 20.01) 1 (<0.01) 1 (<0.01)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

# 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)

Table 13.1.1 Subgroup	Summary of Unsolicited Adverse Ever (18-64)	nts Reported from Day 0 to 49 (28 Days Post   Years)	Confidential e 133 of 140 Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class Preferred Term (# of Subjects)	(n, %, 95% CI) N = 25282	(n, %, 95% CI) N = 16433	(Vaccine - Placebo) (%, 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)	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.09)
Breast cancer	4 (0.02)	(00.0) (00.0)	0.02 (0.00, 0.03)
Melanocytic naevus	4 (0.02)	2 (0.01) and	0.00 (-0.02, 0.03)
Lipoma Malignant melanoma	3 (0.01) 2 (<0.01)	0 (0.90)	0.01 (-0.00, 0.03) 0.01 (-0.00, 0.02)
Uterine leiomyoma	2 (<0.01)	10Pa. Dli (0 (0.00)	0.01 (-0.00, 0.02)
Basal cell carcinoma	1 (<0.01)	enio, app 0 (0.00)	0.00 (-0.00, 0.01)
Benign breast neoplasm	1 (<0.01)	0 (0.00) 0 (0.00) 0 (0.00) 0 (0.00) 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 (2019) COV 101 Port 1, 2019 COV 1

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).

ovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 Table 13.1.1 Subo		Page nts Reported from Day 0 to 49 (28 Days Post D	Confidential e 134 of 140 Pose 2) by Age
	(18-64)		
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(Vaccine - Placebo) (%, 95% Cl) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
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)	e (0.00)	0.00 (-0.00, 0.01)
Anogenital warts	0 (0.00)	20/17 (<0.01)	-0.01 (-0.02, 0.00)
Fibroadenoma of breast	0 (0.00)	1 (<0.01)	-0.01 (-0.02, 0.00)
	eme	europa.eu 1 (<0.01) 3. europa.eu 1 (<0.01) 1 (<0.01) 2. orisation applici (<0.01)	

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

# 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)

19nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV- <b>Table 13.1.1 Sub</b>	group Summary of Unsolicited Adverse Events (18-64 Yea	Reported from Day 0 to 49 (28 Days Post	Confidential ye 135 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.00)
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) and	-0.01 (-0.02, 0.01)
Incoded	14 (0.06), (0.03, 0.09)	e 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) ema.c	1 (<0.01) and (0.03) (0.01, 0.07) 4 (0.02) 0 (0.00) 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 (2019) COV 101 Port 1, 2019 COV 1

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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/20 <b>Table 13.1.1 Subgroup S</b>		Page erse Events Reported from Day 0 to 49 (28 Days Post E (18-64 Years)	Confidential e 136 of 140  Oose 2) by Age
-	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
LEFT ARM PAIN/SORENESS	1 (<0.01)	0 (0.00)	0.00 (-0.00, 0.01)
LEFT LOWER MOLAR TOOTH REMOVAL SECONDARY	1 (<0.01)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.00 (-0.00, 0.01) 0.00 (-0.00, 0.01)
TO INFECTION		1 SUL	
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)	(0.00)	0.00 (-0.00, 0.01)
UPPER LEFT SECOND MOLAR ECTRACTION	0 (0.00)	ouroparapplis (<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)	8/13 (0.02)	0.00 (-0.03, 0.03)
	rketing	0 (0.00) and 0 (0.	

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\_sun\_sub.sas 18JUL2021 20:16 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

# 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)

•	Reported from Day 0 to 49 (28 Days Post Dors)	Confidential 137 of 140 use 2) by Age
Vaccine	Placebo	Risk Difference
(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
N = 25282	N = 16433	(%, 95% CI)
3 (0.01)	0 (0.00)	0.01 (-0.00, 0.03)
1 (<0.01)	0 (0.00)	0.00 (-0.00, 0.01)
1 (<0.01)	1 (<0.01)	-0.00 (-0.02, 0.01)
1 (<0.01)		0.00 (-0.00, 0.01)
1 (<0.01)	1 (<0.07) a	-0.00 (-0.01, 0.01)
11 (0.04), (0.02, 0.08)	6(0.04), (0.01, 0.08)	0.01 (-0.03, 0.05)
4 (0.02)	Uron 200 2 (0.01)	0.01 (-0.02, 0.03)
3 (0.01) ema.e	5ation 0 (0.00)	0.01 (-0.00, 0.02)
	Vaccine (n, %, 95% Cl) N = 25282 3 (0.01) 1 (<0.01) 1 (<0.01)	(n, %, 95% CI) N = 25282 3 (0.01) 1 (<0.01) 1 (<0.01) (n, %, 95% CI) N = 16433 0 (0.00) 0 (0.00) 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.

MedDRA version: 23.0 (2019pCoV 101 Port 1, 2019-20 V 104 Po

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).

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			.2/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI) 0.01 (-0.00, 0.02) 0.00 (-0.00, 0.01)
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) and	-0.01 (-0.02, 0.01)
Hepatic steatosis	0 (0.00)	3 (0,02)	-0.02 (-0.04, 0.00)
		a eu .: catio	
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)	eulo 28 1 (<0.01)	0.01 (-0.01, 0.03)
Pregnancy	2 (<0.01)	na. ation 0 (0.00)	0.01 (-0.00, 0.02)
	e'	risa	
		$^{c}h_{O}$ ,	
	7 30		
	ating	3 (0.08) 3 (0.08) (0.00, 0.04) 1 (<0.01) 0 (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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo 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)

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV- <b>Table 13.1.1 Sub</b>	group Summary of Unsolicited Adverse Events (18-64 Yea	Reported from Day 0 to 49 (28 Days Post	Confidential ye 139 of 140  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class Preferred Term (# of Subjects)	(n, %, 95% CI) N = 25282	(n, %, 95% Cl) N = 16433	(Vaccine - Placebo) (%, 95% Cl) -0.01 (-0.02, 0.00)
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)	12(<0.01)	-0.01 (-0.02, 0.01)
Implantable defibrillator replacement	0 (0.00)	10Pin polly (<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	1 (<0.01) 0 (0.00) 0 (0.00) 0 (0.00) 0 (0.00) ema.	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 (2019) COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019 COV 101

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_1.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

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2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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)

			200
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 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)	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.02, 0.01) -0.01 (-0.02, 0.01)
		7 SUL	
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 (<0,0(1)	-0.01 (-0.02, 0.00)
Partner stress	0 (0.00)	(1a (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)	eul (<0.01)	-0.01 (-0.02, 0.00)
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	61,	isa	
	,th <sup>0</sup>		
	a alle	europa eu 1 (30.01) 2 (0.01) 1 (<0.01)	

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

	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
ny 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)	639 (18.47), (17.19, 19.81) 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) and	1.54 (0.93, 2.15)
Pyrexia	34 (0.71)		0.75 (0.46, 1.04)
Injection site pruritus	28 (0.59)	(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)
	m	12.europa.eu 2 (0.03) 12.europa appli 2 (0.06) 2 (0.06)	
	6.	orise	
	aut'l		
	7 70		

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.

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/20			Confidential ge 2 of 69
Table 13	3.1.2 Subgroup Summary of Unsolicited Adverse Events (>= 65 Yea		Confidential  ge 2 of 69 t Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.38 (0.13, 0.63) 0.43 (0.20, 0.67)
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)	3 (0.09) 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 (0.00)	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)	(0.00) 20/10 (0.00)	0.15 (0.03, 0.28)
Oedema peripheral	6 (0.13)	3 (0.09)	0.01 (-0.13, 0.14)
· ·	ema. s	Europa en (0.03) Sation applico (0.00) 3 (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.

# 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)

	rt2/2019nCoV-301/2019nCoV-302/2019nCoV-501 ble 13.1.2 Subgroup Summary of Unsolicited Adverse Events	9	Confidential 3 of 69 lose 2) by Age
	(>= 65 Yea		
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.07 (-0.07, 0.21) 0.08 (0.00, 0.15)
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)	0 (0.00) 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)	(0.00)	0.10 (0.00, 0.20)
Feeling cold	3 (0.06)	2000, $20110$ (0.00)	0.08 (-0.01, 0.16)
Inflammation	3 (0.06)	3 (0.09)	-0.00 (-0.12, 0.12)
	ema.	Europa.eu 1(0,03) (0.00) (5ation application)	

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

# 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)

	/2019nCoV-301/2019nCoV-302/2019nCoV-501 e 13.1.2 Subgroup Summary of Unsolicited Adverse Events		Confidential ge 4 of 69 t Dose 2) by Age
	(>= 65 Yea	ars)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.05 (-0.05, 0.15) 0.03 (-0.06, 0.11)
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)	1 (0.03) 2 (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)
	ema.	Europa. eu 1 (0,43), Europa applic 2 (0.06) 1 (0.03)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

# 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201		•	Confidential ge 5 of 69
Table 13.	1.2 Subgroup Summary of Unsolicited Adverse Event: (>= 65 Ye		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.07, 0.05) -0.01 (-0.09, 0.08)
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)	1 (0.03) 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)	Ø (0.00)	0.03 (-0.02, 0.08)
Injection site dermatitis	1 (0.02)	2000 (0.00)	0.02 (-0.02, 0.05)
Injection site haematoma	1 (0.02)	2010 1 (0.03)	-0.01 (-0.07, 0.05)
	ema.	europa eu (0.00) 1 (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.

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nC	CoV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Even		Confidential ge 6 of 69 E Dose 2) by Age
Table 13.1.2.	(>= 65 Y	-	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) 0.03 (-0.02, 0.08)
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 (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 (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)	euron apr 0 (0.00)	0.02 (-0.02, 0.05)
	ELLIO	europa, eu 0 (0,00) , europa, eu 2 (0.06) 0 (0.00)	
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	a au		

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.

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Page	Confidential 7 of 69
	Table 13.1.2 Subgroup Summary of Unsolicited Adverse (>=	Events Reported from Day 0 to 49 (28 Days Post Do 65 Years)	Confidential 7 of 69 ose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.03 (-0.02, 0.08) 0.03 (-0.02, 0.08)
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)	0 (0.00) 1 (0.03) any	-0.00 (-0.07, 0.07)
Crepitations	0 (0.00)	1 (0.03)	-0.03 (-0.08, 0.02)
Hyperpyrexia	0 (0.00)	1 (0,93)	-0.03 (-0.08, 0.02)
Impaired healing	0 (0.00)	(0.03)	-0.03 (-0.08, 0.02)
Induration	0 (0.00)	$200^{10.00}$	-0.03 (-0.10, 0.03)
Suprapubic pain	0 (0.00)	1 (0.03)	-0.03 (-0.10, 0.03)
	e'	1 (0.03) and 1 (0.03) and 1 (0.03) and 1 (0.03) and 1 (0.03) 1 (0.03) 1 (0.03) 1 (0.03)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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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2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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)

			:31'
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	- (Vaccine - Placebo) (%, 95% CI) -0.03 (-0.10, 0.03) -0.03 (-0.08, 0.02)
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) and 1 (0.03) 1 (0.03) 2 (0.03) 2 (0.03) 3 (0.03) 3 (0.03) 3 (0.03) 3 (0.03) 3 (0.03) 4 (0.03) 4 (0.03) 4 (0.03) 6 (0.03) 7 (0.03) 7 (0.03) 7 (0.03) 7 (0.03) 7 (0.03) 7 (0.03) 7 (0.03)	-0.03 (-0.08, 0.02)
Musculoskeletal and connective tissue disorders	286 (5.99), (5.33, 6.70)	298 (2.83), (2.31, 3.44)	4.18 (3.25, 5.11)
Pain in extremity	107 (2.24)	ma. cation 14 (0.40)	2.34 (1.80, 2.88)
		thorise	
	and all		
	- Leting		

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 (2019) COV 101 Port 1, 2019, CV 1

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).

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Par	rt2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Pa	Confidential ge 9 of 69
Ta	able 13.1.2 Subgroup Summary of Unsolicited Adverse Events Re (>= 65 Years)		Confidential ge 9 of 69 : Dose 2) by Age
-	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 1.68 (1.15, 2.20) -0.07 (-0.45, 0.31)
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)	29 (0.84) 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	F (0.40)	0 (0 00)	0.13 (0.02, 0.24)
Neck pain	4 (0.08)	0 (0.90) (0.12)	-0.01 (-0.15, 0.13)
Osteoarthritis	4 (0.08)	20/1/3 (0.09)	-0.03 (-0.16, 0.11)
Tendonitis	4 (0.08)	1 (0.03)	0.05 (-0.04, 0.14)
	5 (0.10) 4 (0.08) 4 (0.08) 4 (0.08) ema.eu	ation,	

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.

## 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)

	rt2/2019nCoV-301/2019nCoV-302/2019nCoV-501 ble 13.1.2 Subgroup Summary of Unsolicited Adverse Events F	Reported from Day 0 to 49 (28 Days Post	Confidential ge 10 of 69  Dose 2) by Age
	(>= 65 Year	rs)	riation
-	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.08 (-0.01, 0.16) 0.08 (-0.01, 0.16)
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)	0 (0.00) 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 (0,96)	-0.02 (-0.10, 0.07)
Muscle tightness	2 (0.04)	(0.03)	0.03 (-0.06, 0.11)
Muscular weakness	2 (0.04)	1003, 2011 (0.03)	0.03 (-0.06, 0.11)
Arthritis	1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
	ema.	0 (0.00) 2 (0.96) 2 (0.93) 1 (0.03) 0 (0.00)	
	uthol'	•	

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).

# Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 13.1.2 S	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Event		Confidential ge 11 of 69 Dose 2) by Age
	(>= 65 Ye	•	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.07, 0.07) -0.00 (-0.07, 0.07)
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)	1 (0.03) 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)	<b>(0.03)</b>	-0.00 (-0.07, 0.07)
Intervertebral disc protrusion	1 (0.02)	(0.00)	0.02 (-0.02, 0.05)
Jaw cyst	1 (0.02)	europa en 1 (0.03) europa applica (0.03) 0 (0.00)	0.02 (-0.02, 0.05)
	ma	is ation.	
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	all all		

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

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 <b>Table 13.1.2 Subgroup Summary of Unsolicited Adverse</b>	9	Confidential e 12 of 69 Dose 2) by Age
	(2	>= 65 Years)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.02, 0.05) -0.01 (-0.07, 0.05)
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 (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)	eV : (3(0.03)	-0.02 (-0.09, 0.06)
Pain in jaw	1 (0.02)	2011 (0.03)	-0.01 (-0.09, 0.08)
Rheumatoid arthritis	1 (0.02)	eul 2 apr 1 (0.03)	-0.00 (-0.07, 0.07)
		2 (0.06) and 1 (0.93) and 1 (0.03) 1 (0.03) 1 (0.03) 1 (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).

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV			Confidential ge 13 of 69
Table 13.1.2 S	Subgroup Summary of Unsolicited Adverse Even (>= 65 Y		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.02 (-0.02, 0.05) 0.02 (-0.02, 0.05)
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 (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)	(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)	0 (0.00) 1 (0.03) 1 (0.03) 2 (0.03) 2 (0.03) 1 (0.03) 3 (0.03)	-0.03 (-0.08, 0.02)
	ews	risatio	
	15hC	), .	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)

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	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	
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)	5 (0.4) 14 (0.40)	1.76 (0.87, 2.65)
Headache	142 (2.97)	1, (O) (S) (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)
	uth	Okis	
	ting au		

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 (2019) COV 101 Port 1, 2019, CV 1

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).

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV			Confidential ge 15 of 69
Table 13.1.2	Subgroup Summary of Unsolicited Adverse Event (>= 65 Yo	•	Confidential ge 15 of 69  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% Cl) 0.05 (-0.08, 0.19) 0.07 (-0.04, 0.17)
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) 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)	0 (0 0 m Q	0.03 (-0.09, 0.14)
Taste disorder	3 (0.06)	eV (0.00)	0.08 (-0.01, 0.16)
Paraesthesia	2 (0.04)	20 11 (0.32)	-0.23 (-0.41, -0.05)
Poor quality sleep	2 (0.04)	2 (0.03)	0.03 (-0.06, 0.11)
	ema	2 (0.06) 2 (0.00) 2 (0.00) 2 (0.00) 2 (0.03) 2 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo			Confidential e 16 of 69
Table 13.1.2 3	subgroup Summary of Unsolicited Adverse Ever (>= 65 \		Confidential te 16 of 69  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.04 (-0.02, 0.10) -0.03 (-0.14, 0.09)
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)	3 (0.09) 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)	(0.00)	0.02 (-0.02, 0.05)
Anosmia	1 (0.02)	1 (0.03)	-0.01 (-0.07, 0.05)
Burning sensation	1 (0.02)	euro, 20th 0 (0.00)	0.03 (-0.02, 0.08)
	ews	0 (0.00) 0 (0.00) 0 (0.00) 1 (0.03) 0 (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

## 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)

-	ents Reported from Day 0 to 49 (28 Days Post Years)	2000 27 27 Tigo
	,	Confidential ge 17 of 69  Dose 2) by Age
Vaccine	Placebo	Risk Difference
(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) 0.03 (-0.02, 0.08)
1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
1 (0.02)	1 (0.03)	-0.02 (-0.09, 0.06)
1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
1 (0.02)	0 (0 000 0	0.03 (-0.02, 0.08)
1 (0.02)	2(0.06)	-0.03 (-0.11, 0.04)
1 (0.02)	(0.00)	0.02 (-0.02, 0.05)
1 (0.02)	(0.00) 0 AND 0 (0.00)	0.02 (-0.02, 0.05)
emi	a.g. sation	
	(n, %, 95% CI) N = 4776 1 (0.02) 1 (0.02) 1 (0.02) 1 (0.02)	(n, %, 95% CI) N = 4776 1 (0.02) 1 (0.02)

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

(>=	65	Years)
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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nC Table 13.1.2 S	oV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Event (>= 65 Yo	ts Reported from Day 0 to 49 (28 Days Post	Confidential ge 18 of 69  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.02, 0.05) -0.01 (-0.07, 0.05) 0.02 (-0.02, 0.05)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
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)	(0.03)	-0.03 (-0.08, 0.02)
Loss of consciousness	0 (0.00)	$200^{20}$ $2011$ (0.03)	-0.03 (-0.08, 0.02)
Nerve compression	0 (0.00)	euro apr 1 (0.03)	-0.03 (-0.10, 0.03)
	ema	1 (0.03) 37 europa eu (0.03) 1 (0.03) 1 (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).

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			.311
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.07 (-0.16, 0.03) -0.03 (-0.10, 0.03)
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)
		and	
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)	20 <sup>1</sup> 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)
	61,	risa	
	143 (2.99), (2.53, 3.52) 25 (0.52) 15 (0.31) 10 (0.21) 9 (0.19)	3,	
	and all		
	ating		
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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 (2019) COV 101 Port 1, 2019, CV 1

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).

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo		•	Confidential ge 20 of 69
Table 13.1.2 30	ubgroup Summary of Unsolicited Adverse Ever (>= 65 \		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.12, 0.17) 0.04 (-0.12, 0.21) 0.00 (-0.15, 0.15)
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)	Z(0.20)	-0.07 (-0.25, 0.12)
Oral herpes	4 (0.08)	100 <sup>2</sup> 2011 6 (0.17)	-0.08 (-0.24, 0.09)
Conjunctivitis	3 (0.06)	1 (0.03) and 10 (0.29) and 10 (0.29) and 10 (0.29) and 10 (0.20) and 6 (0.17) o (0.00)	0.06 (-0.01, 0.13)
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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).

ovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 <b>Table 13.1.2 Subgr</b>	oup Summary of Unsolicited Adverse Even	nts Reported from Day 0 to 49 (28 Days Post Do	Confidential 21 of 69 se 2) by Age
	(>= 65 Y	rears)	ariatio.
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.07 (-0.01, 0.15) 0.05 (-0.05, 0.15)
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) any	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 (0.90)	0.03 (-0.01, 0.08)
Abscess rupture	1 (0.02)	2000, $2010$ (0.00)	0.03 (-0.02, 0.08)
Appendicitis	1 (0.02)	1 (0.03)	-0.01 (-0.07, 0.05)
	w <sub>s</sub>	europa eu (0,00) 1, europa appli (0,000) 1 (0.03)	
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Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	01 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	Page 2	Confidential 22 of 69 se 2) by Age
	Table 13.1.2 Subgroup Summary of Unsolicited Adverse (>=	e 65 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.04 (-0.13, 0.05) 0.02 (-0.02, 0.05)
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) A any e	-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)
	e	thorisation applications)	
	al.	ithe	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201 Table 13.	9nCoV-301/2019nCoV-302/2019nCoV-501 1.2 Subgroup Summary of Unsolicited Adverse Events	9	Confidential e 23 of 69 Cose 2) by Age
1.23.6 1.5.	(>= 65 Ye		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.07, 0.05) 0.03 (-0.02, 0.08)
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 (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)	(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)
	ema.	0 (0.00) 0 (0.00) 0 (0.00) 3 (0.06) 1 (0.03) 1 (0.03)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13.1.2 S</b>	ubgroup Summary of Unsolicited Adverse Ev	Pay Vents Reported from Day 0 to 49 (28 Days Post 5 Years)	Confidential ge 24 of 69 Dose 2) by Age
-	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) -0.01 (-0.09, 0.08) 0.03 (-0.02, 0.08)
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)	0 (0.00) 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)	ev (0.00)	0.03 (-0.02, 0.08)
Sepsis	1 (0.02)	1003.2011(0.03)	-0.02 (-0.09, 0.06)
Skin infection	1 (0.02)	na. euror apr 0 (0.00)	0.02 (-0.02, 0.05)
	er aut	0 (0.00) and 0 (0.00) and 0 (0.00) and 0 (0.00) and 1 (0.00) and 1 (0.03) 0 (0.00) and 1 (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. 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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13 1 2 Subgroup Summary of Unsolicited Adver		Confidential 5 of 69 se 2) by Age
		(>= 65 Years)	oriations o
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) 0.02 (-0.02, 0.05)
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 (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)	e (0.00)	0.03 (-0.02, 0.08)
Arthritis bacterial	0 (0.00)	$20^{100}$ $20^{11}$ (0.03)	-0.03 (-0.10, 0.03)
Bacterial infection	0 (0.00)	2 EUT 3 PF 1 (0.03)	-0.03 (-0.08, 0.02)
		1 (0.03) and 0 (0.00) and 0 (0.00) and 0 (0.00) and 1 (0.03) and 1 (0.03) and 1 (0.03) and 1 (0.03)	
		author	

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

## 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)

	s Reported from Day 0 to 49 (28 Days Post I	Confidential e 26 of 69  Cose 2) by Age
Vaccine	Placebo	Risk Difference
(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
N = 4776	N = 3459	(%, 95% CI)
0 (0.00)	3 (0.09)	-0.09 (-0.20, 0.01)
0 (0.00)	5 (0.14)	-0.13 (-0.24, -0.02)
0 (0.00)	1 (0.03)	-0.03 (-0.08, 0.02)
0 (0.00)	2 (0.06)	-0.05 (-0.12, 0.02)
0 (0.00)	1 (0.03)	-0.03 (-0.08, 0.02)
0 (0.00)	(0.06)	-0.06 (-0.14, 0.02)
0 (0.00)	1 (0.03)	-0.03 (-0.08, 0.02)
0 (0.00)	EUTON 2PY 1 (0.03)	-0.03 (-0.08, 0.02)
eu.	risali	
•	Vaccine (n, %, 95% CI) N = 4776 0 (0.00) 0 (0.00) 0 (0.00) 0 (0.00)	Vaccine     Placebo       (n, %, 95% CI)     (n, %, 95% CI)       N = 4776     N = 3459       0 (0.00)     3 (0.09)       0 (0.00)     5 (0.14)       0 (0.00)     1 (0.03)       0 (0.00)     2 (0.06)       0 (0.00)     1 (0.03)       0 (0.00)     2 (0.06)       0 (0.00)     1 (0.03)

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

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30		9	Confidential ge 27 of 69
Table 13.1.2 Subgro	oup Summary of Unsolicited Adverse Even (>= 65 Y	ts Reported from Day 0 to 49 (28 Days Post lears)	Confidential ge 27 of 69  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% Cl) 0.71 (0.07, 1.35) 0.22 (-0.11, 0.55)
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)	1/ (0 40) 0	-0.14 (-0.41, 0.14)
Epistaxis	12 (0.25)	(0.06)	0.24 (0.06, 0.42)
Dyspnoea	8 (0.17)	20/10 (0.29)	-0.09 (-0.31, 0.14)
Productive cough	3 (0.06)	2 (0.03)	0.05 (-0.05, 0.15)
	ema	europa eu (0.46) (0.06) (0.029) (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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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30		•	Confidential e 28 of 69
Table 13.1.2 Subgro	•	ents Reported from Day 0 to 49 (28 Days Post [ 5 Years)	ariations
<u> </u>	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.03 (-0.01, 0.08) -0.07 (-0.19, 0.06)
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)	(0.03)	0.02 (-0.06, 0.10)
Bronchospasm	1 (0.02)	(0.00)	0.03 (-0.02, 0.08)
Chronic obstructive pulmonary disease	1 (0.02)	euron 37 0 (0.00)	0.02 (-0.02, 0.05)
	err ut/	na.europa.eu (0.03) norisation applica (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.

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019n Table 13 1 2	CoV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Even		Confidential age 29 of 69 t Dose 2) by Age
Tuble 13.1.2	(>= 65 Y		oriations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	Vaccine - Placebo) (%, 95% CI) 0.02 (-0.02, 0.05) 0.03 (-0.02, 0.08) 0.02 (-0.02, 0.05)
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(0.0)	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)	eV : (3(0.03)	-0.00 (-0.07, 0.07)
Allergic cough	0 (0.00)	20/1 (0.03)	-0.03 (-0.08, 0.02)
Nasal obstruction	0 (0.00)	1 (0.03)	-0.03 (-0.08, 0.02)
	ELUC	risatio	
	autho	0 (0.00) 2 (0.06) 2 (0.06) 3 (0.03) 1 (0.03) 1 (0.03)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)

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	Vaccine	Placebo	Risk Difference
iystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	Vaccine - Placebo) (%, 95% CI) -0.07 (-0.16, 0.03) -0.03 (-0.08, 0.02)
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)
	400 (0.04) (4.04, 0.70)	21 (2 2 1) (1 2 ( 2 2 2 2 )	0.00 ( 0.44, 0.00)
astrointestinal 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)
	Sı.	risa	
	ithe	),	
	108 (2.26), (1.86, 2.72) 34 (0.71) 24 (0.50) 8 (0.17) 6 (0.13) ema		
	tiris		

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).

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV- Table 13 1 2 Sub	301/2019nCoV-302/2019nCoV-501 group Summary of Unsolicited Adverse Event	-	Confidential ge 31 of 69  Dose 2) by Age
Tuble 10.1.2 oub	(>= 65 Ye		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% Cl) 0.02 (-0.15, 0.18) 0.01 (-0.16, 0.18)
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)	5 (0.14) 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)	EV (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)
	sma	europa eu (0.03) europa applica (0.23) 3 (0.09)	
	200	(120	
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Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 13 1 2 St	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Event	g .	Confidential e 32 of 69 Dose 2) by Age
Table 13.1.2 30	(>= 65 Ye		
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.06, 0.10) 0.05 (-0.02, 0.12)
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)	0 (0.00) 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 (0 000	0.03 (-0.02, 0.08)
Dental caries	1 (0.02)	(0.00)	0.02 (-0.02, 0.05)
Dysphagia	1 (0.02)	(0.00) 0 // 0 (0.00)	0.02 (-0.02, 0.05)
Flatulence	1 (0.02)	(0.00) 0 app 0	0.02 (-0.02, 0.05)
	ema	europa.eu 0 (0.00) europa appli 0 (0.00) o (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.

## 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)

	art2/2019nCoV-301/2019nCoV-302/2019nCoV-501 able 13.1.2 Subgroup Summary of Unsolicited Adverse		Confidential ge 33 of 69  Dose 2) by Age
	<b>.</b> .	= 65 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.07, 0.07) 0.02 (-0.02, 0.05)
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)	20/10 (0.00)	0.02 (-0.02, 0.05)
Mesenteric artery thrombosis	1 (0.02)	0(0.00)	0.02 (-0.02, 0.05)
·	3	ema.europa.eu 0 (0.00)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 13.1.2 S	oV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Event		Confidential ge 34 of 69 t Dose 2) by Age
	(>= 65 Ye	ears)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.07, 0.05) 0.03 (-0.02, 0.08)
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 (0.00)	0.03 (-0.02, 0.08)
Tongue discolouration	1 (0.02)		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)	<b>(0.03)</b>	-0.03 (-0.08, 0.02)
Diverticulum	0 (0.00)	2 (0.06)	-0.05 (-0.12, 0.02)
Food poisoning	0 (0.00)	0 (0.00) and 0 (0.00) and 0 (0.00) and 2 (0.03) europa application (0.03) 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.

## 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)

	2019nCoV-301/2019nCoV-302/2019nCoV-501 13.1.2 Subgroup Summary of Unsolicited Adverse Event		Confidential ge 35 of 69 t Dose 2) by Age
Таше	(>= 65 Ye		
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) -0.03 (-0.08, 0.02) -0.03 (-0.10, 0.03)
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)	1 (0.03) 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 (0.00)	-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)	euro 201 (0.03)	-0.03 (-0.08, 0.02)
	ema	europa eu (0.03) europa appli (0.03) 1 (0.03)	

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

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301 <b>Table 13.1.2 Subgro</b>		nts Reported from Day 0 to 49 (28 Days Post D	Confidential 36 of 69 ose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Injury, poisoning and procedural complications	65 (1.36), (1.05, 1.73)	43 (1.24), (0.90, 1.67)	(Vaccine - Placebo) (%, 95% Cl) 0.16 (-0.35, 0.67) -0.04 (-0.25, 0.18)
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)	eV (0.00)	0.05 (-0.01, 0.11)
Ankle fracture	2 (0.04)	100 <sup>3</sup> 20/10 (0.03)	0.01 (-0.06, 0.08)
Chest injury	2 (0.04)	euro, 30h 0 (0.00)	0.05 (-0.02, 0.12)
	eme	5 (0.14) 21 5 (0.14) 21 1 (0.03) 0 (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. 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).

## 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)

	2019nCoV-301/2019nCoV-302/2019nCoV-501		Confidential ge 37 of 69
Table	13.1.2 Subgroup Summary of Unsolicited Adverse Eve (>= 65	nts Reported from Day 0 to 49 (28 Days Post Years)	Confidential ge 37 of 69 Dose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Dental restoration failure	2 (0.04)	0 (0.00)	(%, 95% CI) 0.03 (-0.01, 0.08) 0.05 (-0.02, 0.12)
Injection related reaction	2 (0.04)	0 (0.00)	0.05 (-0.02, 0.12)
Muscle strain	2 (0.04)	0 (0.00) 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) 2 (0.06)	0.04 (-0.02, 0.10)
Thermal burn	2 (0.04)	(0.06)	-0.01 (-0.10, 0.09)
Tibia fracture	2 (0.04)	(0.00) 0 (0.00)	0.05 (-0.02, 0.12)
Ulna fracture	2 (0.04)	60.00) 0 (0.00)	0.05 (-0.02, 0.12)
	em. auth	a.europa.eu 0 (0.00) 0 (0.00) 0 (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.

(	>=	65	Years)	

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo' <b>Table 13.1.2 Su</b>	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Event	9	Confidential e 38 of 69 Dose 2) by Age
	(>= 65 Yo	ears)	ariation
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) -0.02 (-0.09, 0.06)
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) 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)	(0.00)	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)	en o (0.00)	0.03 (-0.02, 0.08)
	ama	europa eu (0.00) europa appli 2 (0.06) 0 (0.00)	
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	autilia		

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.

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13.1.2 S</b>	oV-301/2019nCoV-302/2019nCoV-501 Subgroup Summary of Unsolicited Adverse Even	g .	Confidential e 39 of 69 Dose 2) by Age
	(>= 65 Y	/ears)	riations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo) (%, 95% CI) -0.03 (-0.11, 0.06) 0.02 (-0.02, 0.05)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 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)	(0.00) 0 (0.00)	0.03 (-0.02, 0.08)
Post procedural erythema	1 (0.02)	enlo 1 3h, 0 (0.00)	0.03 (-0.02, 0.08)
	ema	Leuropa eu 0 (0.00) Drisation appli 0 (0.00)	
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	auth.		

Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.2 Subgroup Summary of Unsolicited Adverse Eve		Confidential ge 40 of 69 Dose 2) by Age
	•	(>= 65 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) 0.02 (-0.02, 0.05) 0.03 (-0.02, 0.08)
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(0.0)	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 (0 000 0	0.03 (-0.02, 0.08)
Road traffic accident	1 (0.02)	0 (0.00)	-0.00 (-0.07, 0.07)
Skin abrasion	1 (0.02)	(0.00)	0.02 (-0.02, 0.05)
Skin laceration	1 (0.02)	euron app 4 (0.12)	-0.09 (-0.21, 0.04)
	m <sub>9</sub>	a.europa.eu (0.00) (0.00) (0.00) (0.12)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Martel-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).

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV			Confidential ge 41 of 69	
Table 13.1.2 Sut	ubgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Pos (>= 65 Years)		Confidential age 41 of 69 st Dose 2) by Age	
	Vaccine	Placebo	Risk Difference	
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)	
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.02 (-0.02, 0.05) 0.02 (-0.02, 0.05)	
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 (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 (0,90)	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)	euro 20 1 (0.03)	-0.03 (-0.08, 0.02)	
	EWS	0 (0.46) 0 (0.46) 2 (0.06) 1 (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).

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			.311
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.03 (-0.10, 0.03) -0.11 (-0.22, -0.00)
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)
		and	
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)	2 (0.03)	0.11 (-0.01, 0.23)
Dermatitis	4 (0.08)	0 (0.00)	0.08 (0.00, 0.15)
	SI,	risas	
	4.	$\nu_0$ ,	
	and all		
	ating	29 (0.84), (9.56, 1.20) (8.0.23) 5 (0.14) 1 (0.03) 0 (0.00)	
	1/6		

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 (2019) COV 101 Port 1, 2019, CV 1

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo		S .	Confidential e 43 of 69
Table 13.1.2 St	ubgroup Summary of Unsolicited Adverse Event (>= 65 Ye	•	Confidential e 43 of 69  Pose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class  Profestred Term (# of Subjects)	(n, %, 95% CI) N = 4776	(n, %, 95% CI) N = 3459	(Vaccine - Placebo) (%, 95% Cl) 0.10 (0.00, 0.20) 0.08 (-0.04, 0.19)
Preferred Term (# of Subjects) Hyperhidrosis	4 (0.08)	0 (0.00)	0.10 (0.00, 0.20)
Night sweats	4 (0.08)	1 (0.03)	0.10 (0.00, 0.20)
Dermal cyst	3 (0.06)	1 (0.03) 0 (0.00)	0.08 (-0.04, 0.17)
Rash erythematous	3 (0.06)	1 (0.03)	0.05 (-0.05, 0.15)
Rash pruritic	0 (0 0 1)	1 (0.10)	-0.05 (-0.17, 0.07)
Skin lesion	2 (0.04)	4 (0.12)	-0.05 (-0.16, 0.06)
Urticaria	2 (0.04)	2003, 2011(3 (0.09)	-0.03 (-0.16, 0.09)
Acne	1 (0.02)	O(0.00)	0.03 (-0.02, 0.08)
	ma	4 (0.12) 4 (0.12) 3 (0.09) 0 (0.00)	
	6,	risc	
	itho		

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019		`	Confidential ge 44 of 69
Table 13.1	.2 Subgroup Summary of Unsolicited Adverse Even (>= 65 Y		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) 0.03 (-0.02, 0.08)
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 (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 (0.96)	-0.03 (-0.11, 0.06)
Hair growth abnormal	1 (0.02)	(0.00)	0.03 (-0.02, 0.08)
Rash macular	1 (0.02)	(0.00) 0 (0.00)	0.03 (-0.02, 0.08)
Rash maculo-papular	1 (0.02)	(0.00) 0 APP 0	0.02 (-0.02, 0.05)
	autho	europa eu 2 (0.00) europa applico (0.00) 0 (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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 20:16

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

		2/1
Vaccine	Placebo	Risk Difference
(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
N = 4776	N = 3459	(%, 95% CI)
1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
1 (0.02)	0 (00.0)	0.02 (-0.02, 0.05)
1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
0 (0.00)	1 (0,93)	-0.03 (-0.08, 0.02)
0 (0.00)	(0.03)	-0.03 (-0.10, 0.03)
0 (0.00)	1100 3 pp// (0.03)	-0.03 (-0.08, 0.02)
59 (1.24), (0.94, 1.59)	na estion 26 (0.75), (0.49, 1.10)	0.56 (0.12, 1.00)
aut	horiz	
eting a		
	(n, %, 95% CI) N = 4776 1 (0.02) 1 (0.02) 1 (0.02) 1 (0.02)	(n, %, 95% CI)  N = 4776  1 (0.02)  1 (0.02)  1 (0.02)  1 (0.02)  1 (0.02)  0 (0.00)  1 (0.02)  0 (0.00)  1 (0.02)  0 (0.00)  1 (0.02)  0 (0.00)  1 (0.03)  0 (0.00)  0 (0.00)  1 (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 (2019 p.Ca.V. 101 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 103 Part 1, 20

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo <b>Table 13.1.2 S</b> u	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Event	9	Confidential 46 of 69 ose 2) by Age
	(>= 65 Ye		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.43 (0.04, 0.83) 0.01 (-0.08, 0.10)
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) 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)	e (0.00)	0.02 (-0.02, 0.05)
Blood pressure fluctuation	1 (0.02)	(0.00) 0 1/O (0.00)	0.02 (-0.02, 0.05)
Deep vein thrombosis	1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
	ews	europa.eu 0 (0.00) europa appli (0.00) 0 (0.00)	

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

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

		.311
Vaccine	Placebo	Risk Difference
(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
N = 4776	N = 3459	(%, 95% CI)
1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
1 (0.02)	0 (0,00)	0.02 (-0.02, 0.05)
0 (0.00)	eV (8.03)	-0.03 (-0.10, 0.03)
0 (0.00)	110pg 3pp/101 (0.03)	-0.03 (-0.10, 0.03)
32 (0.67), (0.46, 0.94)	na. eur 19 (0.55), (0.33, 0.86)	0.16 (-0.18, 0.50)
aut	holis	
ating a		
	(n, %, 95% CI) N = 4776 1 (0.02) 1 (0.02) 1 (0.02)	(n, %, 95% CI) N = 4776 1 (0.02) 1 (0.02) 1 (0.02) 1 (0.02) 0 (0.00) 0 (0.00) 0 (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 (2019) COV 101 Port 1, 2019, CV 1

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile 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)

	//2019nCoV-301/2019nCoV-302/2019nCoV-501 e 13.1.2 Subgroup Summary of Unsolicited Adverse Events R		Confidential ge 48 of 69 Dose 2) by Age
Tabl	(>= 65 Year		. (2)
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.03 (-0.17, 0.24) 0.05 (-0.04, 0.14)
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)	0.40.00	-0.03 (-0.14, 0.07)
Biopsy lymph gland	1 (0.02)	(0.00)	0.02 (-0.02, 0.05)
Blood cholesterol increased	1 (0.02)	(0.00) 0 (0.00)	0.03 (-0.02, 0.08)
Blood iron increased	1 (0.02)	0(0.00)	0.03 (-0.02, 0.08)
	ema.e authoris	uropa. eu 2 (0.00) 0 (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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 20:16

19nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2 <b>Table 13.1.2 Subgroup</b>	Summary of Unsolicited Adverse E	vents Reported from Day 0 to 49 (28 Days Post 55 Years)	Confidential ge 49 of 69  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% Cl)	(%, 95% CI) -0.01 (-0.07, 0.05) 0.02 (-0.02, 0.05)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 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)	(0.00) 0 (0.00)	0.02 (-0.02, 0.05)
Weight decreased	1 (0.02)	0(0.00)	0.02 (-0.02, 0.05)
·		na.europa.eu (0,00) na.europa.applico(0.00) 0 (0.00)	

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

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2 Table 13.1.2 Subgroup	Summary of Unsolicited Adverse Ev	vents Reported from Day 0 to 49 (28 Days Post	Confidential ge 50 of 69 t Dose 2) by Age
	(>= 6	55 Years)	riation
-	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.03 (-0.02, 0.08) -0.03 (-0.08, 0.02)
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)	(0.03)	-0.03 (-0.08, 0.02)
Blood urea nitrogen/creatinine ratio increased	0 (0.00)	2000 2011 (0.03)	-0.03 (-0.10, 0.03)
Light chain analysis increased	0 (0.00)	euro 2 2 (0.03)	-0.03 (-0.08, 0.02)
	en aut	1 (0.03) and 1 (0.03) and 1 (0.03) 3 (0.03) 1 (0.03) 1 (0.03) 1 (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 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)

			3/10
	Vaccine	Placebo	Risk Difference
ystem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Tumour marker increased	0 (0.00)	1 (0.03)	(Vaccine - Placebo) (%, 95% CI) -0.03 (-0.08, 0.02)
letabolism 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) and	0.07 (-0.05, 0.19)
Hypoglycaemia	4 (0.08)	0 (0,00)	0.08 (0.00, 0.15)
Dehydration	3 (0.06)	(0.00)	0.06 (-0.01, 0.13)
Dyslipidaemia	2 (0.04)	2000, 2011,0 (0.00)	0.04 (-0.02, 0.10)
Hyponatraemia	2 (0.04)	enlo 2 3h, 0 (0.00)	0.04 (-0.02, 0.10)
Decreased appetite	1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
	Sr.	risa	
	itho	,	
	4 (0.08) 3 (0.06) 2 (0.04) 2 (0.04) 1 (0.02) ema		
	ating		

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 (2019) COV 101 Port 1, 2019, CV 1

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 Table 13.1.2 Subg		Pa ents Reported from Day 0 to 49 (28 Days Post	Confidential age 52 of 69 t Dose 2) by Age
	(>= 6	5 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.07, 0.07) 0.03 (-0.02, 0.08)
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)	e (0.06)	-0.05 (-0.15, 0.05)
Hypocholesterolaemia	1 (0.02)	2000 0000 (0.00)	0.02 (-0.02, 0.05)
Hypomagnesaemia	1 (0.02)	enles 364 0 (0.00)	0.02 (-0.02, 0.05)
	en	na.europa.eu 0 (0.00) norisation appli 0 (0.00)	

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

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			3/10
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) 0.02 (-0.02, 0.05)
Iron deficiency	1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
Type 2 diabetes mellitus	1 (0.02)	(00.0) 0	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)
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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)	1 (0.03) 1 (0.03) 2270.64), (0.40, 0.96) 4 (0.12) 2 (0.06)	0.03 (-0.09, 0.14)
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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 (2019 p.Ca.V. 101 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 102 Part 1, 2010 a. V. 103 Part 1, 20

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo		•	Confidential e 54 of 69
Table 13.1.2 St	• .	ents Reported from Day 0 to 49 (28 Days Post E 5 Years)	Confidential e 54 of 69  Pose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.00 (-0.12, 0.12) 0.03 (-0.01, 0.08) 0.03 (-0.06, 0.11)
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) and	-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)	(0.03)	-0.02 (-0.09, 0.06)
Myocarditis	1 (0.02)	$200^{3}$ , $20/10^{0}$ (0.00)	0.02 (-0.02, 0.05)
Sinus bradycardia	1 (0.02)	1 (0.03) 0 (0.00) 0 (0.00) 3 (0.03) 0 (0.00) 0 (0.00)	0.02 (-0.02, 0.05)

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mapfel-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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV- <b>Table 13.1.2 Sub</b>		Pa ents Reported from Day 0 to 49 (28 Days Post	Confidential age 55 of 69 t Dose 2) by Age
	(>= 65	Years)	oriations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	Vaccine - Placebo) (%, 95% CI)  -0.03 (-0.13, 0.06) -0.07 (-0.16, 0.03) -0.03 (-0.08, 0.02)
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 (0.00)	-0.03 (-0.10, 0.03)
Bundle branch block right	0 (0.00)	<b>(0.03)</b>	-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)	a.europa.eu 1(0,03) 1 (0.03) 2 (0,03)	-0.03 (-0.08, 0.02)
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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.

## 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	1 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 13.1.2 Subgroup Summary of Unsolicited Adverse Event (>= 65 Ye	Page 56 ts Reported from Day 0 to 49 (28 Days Post Dose	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.08 (-0.21, 0.36) -0.02 (-0.17, 0.13)
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)	(0.00)	0.04 (-0.02, 0.10)
Ear congestion	1 (0.02)	$100^{2}$ $1000$	-0.00 (-0.07, 0.07)
Ear discomfort	1 (0.02)	2 (0.06)	-0.03 (-0.11, 0.06)
	ema autho	3 (0.09) and 0 (0.00) 0 (0.00) and 1 (0.00) 2 (0.06) application application 2 (0.06)	

Note: Risk difference and its Confidence Intervals (CIs) are computed from Markel-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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 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)

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV- <b>Table 13.1.2 Sub</b>	-301/2019nCoV-302/2019nCoV-501 group Summary of Unsolicited Adverse Events (>= 65 Yea	Reported from Day 0 to 49 (28 Days Post Do	Confidential 57 of 69 ose 2) by Age
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Eustachian tube dysfunction	1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
Excessive cerumen production	1 (0.02)	1 (0.03)	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) -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)	(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)	puron apr 1 (0.03)	-0.03 (-0.08, 0.02)
Eye disorders	17 (0.36), (0.21, 0.57) 15 (0.31) 2 (0.04) 0 (0.00) 0 (0.00) 16 (0.34), (0.19, 0.54) ema.e	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.

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101	Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501	g .	Confidential 58 of 69
	Table 13.1.2 Subgroup Summary of Unsolicited Adverse E (>= (	vents Reported from Day 0 to 49 (28 Days Post D 65 Years)	ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Cataract	2 (0.04)	2 (0.06)	-0.01 (-0.10, 0.08) 0.05 (-0.02, 0.12)
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)	EU (3(0.03)	-0.00 (-0.07, 0.07)
Diplopia	1 (0.02)	(0.00) 0 (0.00)	0.02 (-0.02, 0.05)
Dry eye	1 (0.02)	euro, 3Pr 0 (0.00)	0.03 (-0.02, 0.08)
	er a aut	thorisation applica (0.00)	

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 13 1 2 Si	V-301/2019nCoV-302/2019nCoV-501 ubgroup Summary of Unsolicited Adverse Ever	9	Confidential e 59 of 69  Pose 2) by Age
Table 15.1.2 50	(>= 65 \		ariations
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI) 0.03 (-0.02, 0.08) 0.03 (-0.02, 0.08)
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)	0 (0.00) 2 (0.06) 1 (0.03) and any 6	-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)	(0.03)	-0.03 (-0.08, 0.02)
Eye irritation	0 (0.00)	$100^{3}$ , $20/(10.03)$	-0.03 (-0.10, 0.03)
Eye pain	0 (0.00)	1 (0.03)	-0.03 (-0.08, 0.02)
	EWIC	1 (0.03) and 0 (0.00) and 0 (0.00) and 0 (0.00) and 1 (0.03) 1 (0.03) 1 (0.03) Orisation application a	
	ith	2,	

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoFile Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_sub.sas\_BJUL2021 20:16

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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)

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	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.03 (-0.08, 0.02) -0.03 (-0.08, 0.02)
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 Acute kidney injury Urinary retention Haematuria Chronic kidney disease	16 (0.34), (0.19, 0.54) 5 (0.10) 3 (0.06) 2 (0.04) 1 (0.02)	9 (0.26), (0.12, 0.49) 3 (0.09) 0 (0.00) 2 (0.06) 0 (0.00)	0.08 (-0.15, 0.31) 0.01 (-0.12, 0.14) 0.07 (-0.01, 0.15) -0.01 (-0.10, 0.08) 0.02 (-0.02, 0.05)
	ting auth		

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			.21'
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Dysuria	1 (0.02)	2 (0.06)	
Nocturia	1 (0.02)	1 (0.03)	-0.00 (-0.07, 0.07)
Pollakiuria	1 (0.02)	1 (0.03) 1 (0.03)	-0.02 (-0.09, 0.06)
Polyuria	1 (0.02)	0 (0.00) and	0.03 (-0.02, 0.08)
Proteinuria	1 (0.02)	0 (0,00)	0.02 (-0.02, 0.05)
Urinary incontinence	1 (0.02)	@(0.00)	0.02 (-0.02, 0.05)
Urinary tract obstruction	1 (0.02)	1000 30p/10 (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)
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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 (2019) COV 101 Port 1, 2019 COV 1

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo 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)

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-10	on Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501  Table 13.1.2 Subgroup Summary of Unsolicited Adverse	Page 6:	
		= 65 Years)	criations o
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) 0.01 (-0.09, 0.11) -0.09 (-0.23, 0.06)
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)	6 (0.17) 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)	(0.00) 0 (0.00)	0.03 (-0.02, 0.08)
Restlessness	1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
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	2 8	utho	

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.

## 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)

	Years)	Confidential 3 of 69 se 2) by Age
Vaccine	Placebo	Risk Difference
(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
N = 4776	N = 3459	(%, 95% CI)
0 (0.00)	1 (0.03)	-0.03 (-0.08, 0.02)
0 (0.00)	1 (0.03)	-0.03 (-0.08, 0.02)
0 (0.00)	1 (0.00)	-0.03 (-0.08, 0.02)
11 (0.23), (0.12, 0.41)	13 (0.38), (0.20, 0.64)	-0.15 (-0.39, 0.09)
3 (0.06)	(0.00) 0 (0.00)	0.05 (-0.01, 0.11)
2 (0.04)	2 (0.06)	-0.02 (-0.12, 0.09)
2 (0.04)	1 (0.03)	-0.00 (-0.08, 0.08)
1 (0.02)	0 (0.00)	0.02 (-0.02, 0.05)
	(n, %, 95% CI) N = 4776 0 (0.00) 0 (0.00)	(n, %, 95% CI) N = 4776 0 (0.00) 0 (0.00) 1 (0.03) 0 (0.00) 1 (0.03) 1 (0.03) 1 (0.03)

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\_sun\_sub\_sas 18JUL2021 20:16 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

Vaccine (n, %, 95% CI) N = 4776	Placebo (n, %, 95% CI) N = 3459	Confidential ge 64 of 69 Dose 2) by Age  Risk Difference (Vaccine - Placebo)
N = 4776	(n, %, 95% CI) N = 3450	(Vaccine - Placebo)
	IN = 3437	(%, 95% CI)
1 (0.02) 1 (0.02) 1 (0.02) 0 (0.00) 0 (0.00) 0 (0.00) 0 (0.00) 0 (0.00)	0 (0.00) 1 (0.03) and arry	-0.02 (-0.09, 0.06)
	1 (0.02) 0 (0.00)	1 (0.02) 0 (0.00) 0 (0.00) 1 (0.03) 0 (0.00) 1 (0.03) 0 (0.00) 2 (0.03) 0 (0.00) 1 (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.

## 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)

9nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 <b>Table 13.1.2 Sub</b> g	301/2019nCoV-302/2019nCoV-501 group Summary of Unsolicited Adverse Even (>= 65 Y	ts Reported from Day 0 to 49 (28 Days Post	Confidential ge 65 of 69  Dose 2) by Age
	Vaccine	Placebo	Risk Difference
stem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% CI) -0.03 (-0.08, 0.02) -0.03 (-0.08, 0.02)
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) and	-0.03 (-0.08, 0.02)
nmune 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)	(00.0) 0 1/0 (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)	1 (0.03) and (0.03) and (0.03) and (0.04) and (0.04) (0.01) (0.00) (0.00) (0.00) (0.00) (0.00)	0.03 (-0.02, 0.08)
	*170	2/13	

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.

MedDRA version: 23.0 (2019) COV 101 Port 1, 2019 COV 1

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

2nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 Table 13.1.2 Subç		nts Reported from Day 0 to 49 (28 Days Post D	Confidential e 66 of 69 lose 2) by Age
	Vaccine	Placebo	Risk Difference
tem Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
referred Term (# of Subjects)	N = 4776	N = 3459	(Vaccine - Placebo) (%, 95% Cl) 0.03 (-0.02, 0.08) -0.01 (-0.07, 0.05)
ood allergy	1 (0.02)	0 (0.00)	0.03 (-0.02, 0.08)
ypersensitivity	1 (0.02)	1 (0.03)	-0.01 (-0.07, 0.05)
lultiple allergies	1 (0.02)	0(0.00)	0.02 (-0.02, 0.05)
llergy to arthropod bite	0 (0.00)		-0.03 (-0.08, 0.02)
productive system and breast disorders	7 (0.15), (0.06, 0.30)	5 (0.14) (0.05, 0.34)	0.00 (-0.18, 0.18)
rectile dysfunction	2 (0.04)	$200_{3}$ , $20/10$ (0.00)	0.04 (-0.02, 0.10)
reast cyst	1 (0.02)	O(0.00)	0.03 (-0.02, 0.08)
rostatic mass	1 (0.02)	1 (0.03) and 1 (0.03) and 1 (0.03) and 1 (0.04) (0.05, 0.34) (0.00) (0.00) (0.00) (0.00) (0.00)	0.02 (-0.02, 0.05)
	, h'	oris	

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 (2019) COV 101 Port 1, 2019 COV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_subsas 18JUL2021 20:16

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			ariae
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Scrotal swelling	1 (0.02)	0 (0.00)	(Vaccine - Placebo) (%, 95% CI) 0.03 (-0.02, 0.08) -0.04 (-0.13, 0.05)
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)		-0.03 (-0.10, 0.03)
Prostatomegaly	0 (0.00)	1 (0,03)	-0.03 (-0.08, 0.02)
Testicular cyst	0 (0.00)	(0.03)	-0.03 (-0.10, 0.03)
Uncoded	4 (0.08), (0.02, 0.21)	1 (0.03) 1 (0.03) 1 (0.03) 2 (0.03) 3 (0.02, 0.25) 3 (0.09)	0.03 (-0.11, 0.16)
Uncoded	4 (0.08)	18. cation 3 (0.09)	0.03 (-0.11, 0.16)
	الر	Ooklas	
	a Bull	, ·	
	ting		

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo 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)

Table 13.1.2 S	• •	Page 68 ents Reported from Day 0 to 49 (28 Days Post Dos 5 Years)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo) (%, 95% CI) -0.01 (-0.07, 0.05) 0.02 (-0.02, 0.05)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 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)		-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)	eV (2.03)	-0.00 (-0.07, 0.07)
Cholelithiasis	0 (0.00)	auropa, applica (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) en	1 (0.03), (0.00, 0.16) 1 (0.03), (0.00, 0.16) 2 (0.03) 1 (0.03) 4 (0.12), (0.03, 0.30) 1 (0.03)	-0.01 (-0.07, 0.05)

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 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.

	2019nCoV-301/2019nCoV-302/2019nCoV-501 13.1.2 Subgroup Summary of Unsolicited Adverse Events I	Page 6	Confidential 9 of 69 se 2) by Age
	(>= 65 Yea		riations
-	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 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)	
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)	03.eU (1cb(0.03)	-0.03 (-0.08, 0.02)
	ema.e	1 (0.03), (0.00, 0.16) 1 (0.03), (0.00, 0.16) 1 (0.03), (0.03) 1 (0.03), (0.00, 0.16) 2 (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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCo File Name: t13\_1\_2.rtf. Generated from t\_unsol\_sum\_sub.sas 18JUL2021 20:16

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(fate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	(Vaccine - Placebo) (Fate per 100 person-years, 95% CI)
otal follow-up time (person-years)	6337.9	4074.4	telle
verage follow-up time (days)	91.6	90.6	
Median follow-up time (days)	93	4074.4 90.6 92	
ny SAEs	208 (3.28), (2.85, 3.76)	90.6 92 144 (3.53), (2.98, 4.16) 417(.01), (0.72, 1.37) 6 (0.15) 9 (0.22)	-0.71 (-1.46, 0.04)
nfections 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)	scation 9 (0.22)	-0.19 (-0.36, -0.01)
	author	15	
	ating as		

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 (2019) COV 101 Port 1, 2010, 2011 (1917) COV 101 Port 1, 2011 (191

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201	9nCoV-301/2019nCoV-302/2019nCoV-501 up Summary of Event Rates of Serious Adverse Events	•	Confidential 2 of 35 ind of Follow-up) by Age
Table 201111 cabyles	(18-64 Ye		ariations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	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)	O(0.00)	0.01 (-0.01, 0.04)
	ema.	1 (0.02) 0 (0.00) 0 (0.00) 1 (0.02) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019r Table 28 1 1 Subgroup	nCoV-301/2019nCoV-302/2019nCoV-501 Summary of Event Rates of Serious Adverse Events	· · · · · · · · · · · · · · · · · · ·	Confidential 3 of 35 Ind of Follow-up) by Age
Tublo 25.111 Subg. Sup	(18-64 Yes		ariations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Localised infection	1 (0.02)	0 (00.0)	0.01 (-0.01, 0.04)
Mastitis	1 (0.02)	0 (00.0)	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 (0,00)	0.01 (-0.01, 0.04)
Perineal abscess	1 (0.02)	(0.00)	0.01 (-0.01, 0.04)
Pharyngeal abscess	1 (0.02)	2000000000000000000000000000000000000	0.02 (-0.02, 0.06)
Post procedural infection	1 (0.02)	2010.0 (0.00)	0.01 (-0.01, 0.04)
	ema.	europa.eu 0 (0,40) (0,00) (1,5ation applico (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Rep		ğ	Confidential 4 of 35 nd of Follow-up) by Age
	(18-64 Ye	ears)	riations
-	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Postoperative wound infection	1 (0.02)	0 (00.0)	0.02 (-0.02, 0.06)
Pulmonary tuberculosis	1 (0.02)	(00.0) 0	0.02 (-0.02, 0.06)
Pyelonephritis	1 (0.02)	0 (0.00)	0.01 (-0.01, 0.04)
Sepsis	1 (0.02)	1 (0.92)	-0.01 (-0.08, 0.05)
Septic shock	1 (0.02)	3(0.02)	-0.01 (-0.08, 0.05)
Staphylococcal infection	1 (0.02)	2000 0000 (0.00)	0.01 (-0.01, 0.04)
Subcutaneous abscess	1 (0.02)	enro, 2h, 0 (0.00)	0.01 (-0.01, 0.04)
	ema.	europa.eu (0.02) europa.applico(0.00) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019 Table 28.1.1 Subgrou	PnCoV-301/2019nCoV-302/2019nCoV-501 p Summary of Event Rates of Serious Adverse Events (18-64 Yea	Reported During the Study (from Day 0 to E	Confidential 5 of 35 nd of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Urosepsis	1 (0.02)	0 (00.0) 0	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)	3 (0.07) 3 (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)
	ema. authori	Juropa eu 3 (0.02) Juropa applica (0.02) 1 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Repo		Page 6	Confidential 5 of 35 and of Follow-up) by Age
	(18-64 Yea	ars)	riations
	Vaccine	Placebo	Risk Difference
-	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	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) and	-0.03 (-0.08, 0.03)
Injury, poisoning and procedural complications	28 (0.44), (0.29, 0.64)	1 (0.02) and (0.26, 0.70) (0.26, 0.70) (0.00) (0.00) (0.00) (0.00) (0.00) (0.00)	-0.03 (-0.31, 0.25)
Ankle fracture	4 (0.06)	(0.00) (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)
	ithor	(3	
	ing au		

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 (2019) COV 101 Port 1, 2019 COV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub\_sast 8JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019 Table 28 1.1 Subgrou	9nCoV-301/2019nCoV-302/2019nCoV-501 up Summary of Event Rates of Serious Adverse Events	3	Confidential 7 of 35 nd of Follow-up) by Age
Table 20111 caby co	(18-64 Yea		ariations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Burns third degree	1 (0.02)	(00.0) 0	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)	(0.00)	0.02 (-0.02, 0.06)
Fibula fracture	1 (0.02)	2010 1 (0.02)	-0.01 (-0.08, 0.05)
Gun shot wound	1 (0.02)	20(0.00)	0.01 (-0.01, 0.04)
	ema.	1 (0.02) 2 (0.05) 3 (0.00) 1 (0.02) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201	9nCoV-301/2019nCoV-302/2019nCoV-501 up Summary of Event Rates of Serious Adverse Events	9	Confidential 8 of 35 nd of Follow-up) by Age
Table 20.1.1 Subgrou	(18-64 Ye		ariations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Incisional hernia	1 (0.02)	(00.0) 0	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)	3 (0.0₹) (0.00)	0.01 (-0.01, 0.04)
Rib fracture	1 (0.02)	1000 $1000$	-0.01 (-0.08, 0.05)
Skin laceration	1 (0.02)	0(0.00)	0.02 (-0.02, 0.06)
	ema.	europa.eu 3 (0.00) europa.applic 1 (0.02) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201	19nCoV-301/2019nCoV-302/2019nCoV-501 up Summary of Event Rates of Serious Adverse Events	· ·	Confidential 9 of 35 nd of Follow-up) by Age
Table 20.1.1 Subgrou	(18-64 Ye		ariations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Snake bite	1 (0.02)	(00.0) 0	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 (0.92)	-0.00 (-0.06, 0.06)
Tibia fracture	1 (0.02)	2(0.02)	-0.01 (-0.08, 0.05)
Traumatic haematoma	1 (0.02)	2000 DOMO (0.00)	0.01 (-0.01, 0.04)
Wrist fracture	1 (0.02)	0(0.00)	0.01 (-0.01, 0.04)
	ema.	europa.eu (0,02)  europa.applico(0.00) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Repor		•	Confidential 10 of 35 Ind of Follow-up) by Age
Table 20. 1.1 Subgroup 30	(18-64 Ye		ariations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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)	(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)	eul 3P 1 (0.02)	-0.03 (-0.08, 0.03)
	ema.	europa, eu 1 (0,02) 2 (0,02) 1 (0,02) 1 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events (18-64 Yea		Reported During the Study (from Day 0 to B	Confidential 11 of 35 End of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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)	(0.02)	-0.00 (-0.07, 0.07)
Acute coronary syndrome	1 (0.02)	(0.00) 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)
	ema.	Europa, eu 3 (967) Europa, applica (0.00) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Repo (18-64 Years)		s Reported During the Study (from Day 0 to I	Confidential 12 of 35 End of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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)	0 (0.90)	-0.01 (-0.08, 0.05)
Myocarditis	1 (0.02)	2011 (0.02)	-0.01 (-0.08, 0.06)
Palpitations	1 (0.02)	euro, 274 0 (0.00)	0.01 (-0.01, 0.04)
	ema,	europa eu (0.00) europa appli 1 (0.02) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Re (18-64 Years)		Reported During the Study (from Day 0 to I	Confidential 13 of 35 End of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Atrial flutter	0 (0.00)	1 (0.02)	-0.02 (-0.06, 0.02)
Cardio-respiratory arrest	0 (0.00)	1 (0 00)	-0.03 (-0.08, 0.03)
		and	
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)	(0.00)	0.07 (0.01, 0.13)
Migraine	2 (0.03)	2000, $20110$ (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)	13 (0.32), (0.17, 0.55)  13 (0.32), (0.17, 0.55)  20 (0.00)  10 (0.00)  1 (0.02)	-0.00 (-0.07, 0.07)
	EI, J.	1500	
	itho.		
	and an		
	tiris		

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 (2019) COV 101 Port 1, 2019, CV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Rep		Confidential Page 14 of 35 Its Reported During the Study (from Day 0 to End of Follow-up) by Age Years)	
	(18-64 Ye	ears)	riations
-	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Alcoholic seizure	1 (0.02)	0 (0.00)	0.01 (-0.01, 0.04)
Altered state of consciousness	1 (0.02)	(00.0) 0	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)	(0.00)	0.01 (-0.01, 0.04)
Neuropathy peripheral	1 (0.02)	2010 (0.00)	0.01 (-0.01, 0.04)
Peroneal nerve palsy	1 (0.02)	eulo, 20, 0 (0.00)	0.01 (-0.01, 0.04)
	ema.	europa.eu 0 (0.00) europa.applico (0.00) o (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Report		Confidential Page 15 of 35 Reported During the Study (from Day 0 to End of Follow-up) by Age rs)	
Table 26.1.1 Subgroup	(18-64 Ye		oriations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Sciatica	1 (0.02)	(00.0) 0	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)	EV (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)	eul (0.02)	-0.03 (-0.08, 0.03)
	ema.	europa eu (1 (0,02) 1 (0,02) 1 (0,02) 1 (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.

lovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Re (18-64 Years		^3	
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Lumbar radiculopathy	0 (0.00)	1 (0.02)	-0.02 (-0.06, 0.02)
Migraine with aura	0 (0.00)	1 (0.02) 1 (0.02) 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 (0.95)	-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)	2000) O (0.00)	0.03 (-0.01, 0.06)
Abdominal pain	1 (0.02)	0 (0.00)	0.01 (-0.01, 0.04)
	0 (0.00)  17 (0.27), (0.16, 0.43) 2 (0.03) 1 (0.02)  ema.e		

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 (2019) COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019, 2019 COV 101 Port 1, 2019 COV 101

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Repor		•	Confidential 17 of 35 nd of Follow-up) by Age
Table 201111 caby, cap (	(18-64 Ye		ariations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Alcoholic pancreatitis	1 (0.02)	(00.0) 0	0.01 (-0.01, 0.04)
Ascites	1 (0.02)	0 (0.00) 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)	(0.00)	0.02 (-0.02, 0.06)
Haematemesis	1 (0.02)	1 (0.02)	-0.01 (-0.08, 0.05)
Hiatus hernia	1 (0.02)	eulo (0.00)	0.01 (-0.01, 0.04)
	ema.	europa eu (0,000) europa appli (1,0.02) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Repo		Confidential Page 18 of 35 s Reported During the Study (from Day 0 to End of Follow-up) by Age ears)	
	(18-64 Ye	ears)	riations
-	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Impaired gastric emptying	1 (0.02)	1 (0.02)	-0.01 (-0.08, 0.05)
Mallory-Weiss syndrome	1 (0.02)	0 (00.0)	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)	(0.00)	0.01 (-0.01, 0.04)
Rectal haemorrhage	1 (0.02)	2010 (0.00)	0.01 (-0.01, 0.04)
Upper gastrointestinal haemorrhage	1 (0.02)	enion 3h, 0 (0.00)	0.02 (-0.02, 0.06)
	ema	europa.eu 0 (0,40) europa.applico (0.00) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Rej (18-64 Years)		Reported During the Study (from Day 0 to E	Confidential 19 of 35 End of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	(11, Tate per 100 person-years, 95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Duodenal ulcer	0 (0.00)	1 (0.02)	-0.03 (-0.08, 0.03)
Gastric haemorrhage	0 (0.00)	1 (0.02) 1 (0.02)	-0.03 (-0.08, 0.03)
Gastritis erosive	0 (0.00)	1 (0.02) and	-0.02 (-0.06, 0.02)
Hepatobiliary disorders Cholecystitis acute	12 (0.19), (0.10, 0.33) 5 (0.08)	0 (0.00); (NA, 0.09) 0 (0.00)	0.17 (0.07, 0.26) 0.07 (0.01, 0.13)
Cholecystitis	3 (0.05)	0(0.0)	0.05 (-0.01, 0.10)
Bile duct stone	2 (0.03)	0 (0.00)	0.03 (-0.01, 0.06)
	12 (0.19), (0.10, 0.33) 5 (0.08) 3 (0.05) 2 (0.03)  ema.e		

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 (2019) COV 101 Port 1, 2019 COV 1

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

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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)

			3(10
·	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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)
		and	
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)	(0.05)	-0.02 (-0.11, 0.07)
Bipolar disorder	2 (0.03)	100.00 (0.00)	0.03 (-0.01, 0.06)
Depression	2 (0.03)	2 (0.02)	-0.00 (-0.07, 0.06)
Acute psychosis	1 (0.02)	0 (0.00)	0.02 (-0.02, 0.06)
	6/,	isac	
	1440	•	
	all all		
	12 (0.19), (0.10, 0.33) 3 (0.05) 2 (0.03) 2 (0.03) 1 (0.02) emag		
	.XV		

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 (2019pCoV 101 Port 1, 2019-20 V 104 Po

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019 Table 28.1.1 Subgrou	9nCoV-301/2019nCoV-302/2019nCoV-501 p Summary of Event Rates of Serious Adverse Events (18-64 Yea	Page 2 Reported During the Study (from Day 0 to Ed	Confidential 21 of 35 nd of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	(rate per 100 person-years, 95% CI)
Drug abuse	1 (0.02)	1 (0.00)	-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 (0.90) (0.02)	0.01 (-0.01, 0.04)
Alcohol abuse	0 (0.00)	(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)	2011 apr 1 (0.02)	-0.03 (-0.08, 0.03)
	ema. a authori	Juropa appli 1 (0.02) 1 (0.02) 1 (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 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)

			3/10
	Vaccine	Placebo	Risk Difference
•	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Schizophrenia	0 (0.00)	1 (0.02)	-0.02 (-0.06, 0.02)
		Yans L	
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)	(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)	60.00) 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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	74,	0,	
	alle		
	ring	a.europa.eu 2(0.02) 0 (0.00) 1 (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 (2019pCoV 101 Port 1, 2019-20 V 104 Po

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub\_sas\_18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301 Table 28.1.1 Subgroup Summar		Page 2 Reported During the Study (from Day 0 to En	
	Vaccine	Placebo	Risk Difference
_	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Chronic obstructive pulmonary disease	1 (0.02)	0(0.0)	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)	1002 eu nica(0.02)	-0.03 (-0.08, 0.03)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (0.17), (0.09, 0.31)	euron 26 (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)
	arketing aue	1 (0.02) and 1 (0.02) and 1 (0.02) 2 (0.02) 2 (0.15), (0.05, 0.32) 0 (0.00)	

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 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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201 Table 28.1.1 Subgrou	9nCoV-301/2019nCoV-302/2019nCoV-501 up Summary of Event Rates of Serious Adverse Events	9	Confidential 24 of 35 nd of Follow-up) by Age
v	(18-64 Ye		riations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Prostate cancer	2 (0.03)	(00.0) 0	0.03 (-0.01, 0.06)
Bladder cancer	1 (0.02)	0(00.0)	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)	(0.00)	0.01 (-0.01, 0.04)
Malignant melanoma	1 (0.02)	2010 (0.00)	0.01 (-0.01, 0.04)
Testis cancer	1 (0.02)	EURON 3PN 0 (0.00)	0.01 (-0.01, 0.04)
	enthor	europa.eu 0 (0.00) europa.applico (0.00) 0 (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.

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 28.1.1 Subgroup Su	immary of Event Rates of Serious Adverse Events (18-64 Ye	Reported During the Study (from Day 0 to	Confidential 25 of 35 End of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	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)	1003. EU (10.02)	-0.02 (-0.06, 0.02)
Vascular disorders	8 (0.13), (0.05, 0.25)	25 (0.12), (0.04, 0.29)	-0.03 (-0.17, 0.11)
Hypertension	3 (0.05) ema.	1 (0.02) and 1 (0.02) and 1 (0.02) and 2 (0.02) and 3 (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 (2019) COV 101 Port 1, 2019, CV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 <b>Table 28.1.1 Subgroup Summ</b> a		s Reported During the Study (from Day 0 to	Confidential e 26 of 35 End of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
_	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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)	100 a.eu (2)(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) ema	2 (0.05) and 0 (0.00) and 0 (0.02) europa eu nica (0.02) europa a 2 (0.05), (0.01, 0.18) 1 (0.02)	0.02 (-0.06, 0.10)
	ating as		

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 (2019) COV 101 Port 1, 2019 COV 1

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

•	Page 2 Reported During the Study (from Day 0 to Er	Confidential 7 of 35 ad of Follow-up) by Age
Vaccine	Placebo	Risk Difference
(n, rate per 100 person-years,	(n, rate per 100 person-years,	Vaccine - Placebo)
95% CI)	95% CI)	(rate per 100 person-years,
N = 25282	N = 16433	95% CI)
2 (0.03)	0 (0.00)	0.03 (-0.01, 0.06)
1 (0.02)	0 (0.00)	0.01 (-0.01, 0.04)
0 (0.00)	1 (0.02) and	-0.02 (-0.06, 0.02)
5 (0.08), (0.03, 0.18) 1 (0.02) 1 (0.02) 1 (0.02)	evropa ev (0.05) (0.01, 0.18) 0 (0.00) 0 (0.00) 0 (0.00)	0.03 (-0.07, 0.12) 0.02 (-0.02, 0.06) 0.01 (-0.01, 0.04) 0.01 (-0.01, 0.04)
	Waccine (n, rate per 100 person-years, 95% CI) N = 25282 2 (0.03) 1 (0.02) 0 (0.00)	Vaccine   Placebo   (n, rate per 100 person-years, 95% Cl)   N = 25282   N = 16433   2 (0.03)   0 (0.00)   1 (0.02)   0 (0.00)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.02)   1 (0.00)   1

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sast 18JUL2021 20:59

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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)

			. 2 1 1
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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)
	ting auth	1 (0.92) 1 (0.92) 4 (0.10), (0.03, 0.25) 2 (0.05) 0 (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 (2019) COV 101 Port 1, 2019 COV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas 18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nC Table 28.1.1 Subgroup S	Summary of Event Rates of Serious Adverse Events	Page 2 Reported During the Study (from Day 0 to Er	Confidential 29 of 35 nd of Follow-up) by Age
	(18-64 Yea	nrs)	orizitio''
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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) and	-0.03 (-0.08, 0.03)
Metabolism and nutrition disorders Diabetic ketoacidosis	3 (0.05), (0.01, 0.14) 1 (0.02)	(0.20) (0.08, 0.39) 0 (0.00)	-0.18 (-0.34, -0.02) 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)	Sation 0 (0.00)	0.01 (-0.01, 0.04)
	ating author	1 (0.02) and (0.20) (0.08, 0.39) (0.00) (0.00) (0.00) (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 (2019) COV 101 Port 1, 2019 COV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub\_sast 8JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 28.1.1 Subgroup Summa	ary of Event Rates of Serious Adverse Events	Reported During the Study (from Day 0 to E	Confidential 30 of 35 End of Follow-up) by Age
	(18-64 Yea	ars)	ariation
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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) and	-0.03 (-0.08, 0.03)
Hypoglycaemia	0 (0.00)	1 (0,92)	-0.03 (-0.08, 0.03)
Hypokalaemia	0 (0.00)	(0.05)	-0.06 (-0.13, 0.02)
Hyponatraemia	0 (0.00)	suropa applica (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)
	oting author	1 (0.02) and 1 (0.02) and 2 (0.02) and 2 (0.05) and 3 (0.05) (0.02) and 3 (0.07), (0.02, 0.22)	

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 (2019) COV 101 Port 1, 2019 COV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub\_sast 8JUL2021 20:59

Table 28.1.1 Subgroup	o Summary of Event Rates of Serious Adverse Events (18-64 Yea		Confidential 31 of 35 End of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
iystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Arthralgia	1 (0.02)	0 (0.00)	0.01 (-0.01, 0.04)
Intervertebral disc protrusion	1 (0.02)	0 (0.00) 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 (0,92)	-0.03 (-0.08, 0.03)
Musculoskeletal pain	0 (0.00)	(0.02)	-0.02 (-0.06, 0.02)
Neck pain	0 (0.00)	0 (0.00) and 1 (0.02) and 2 (0.02) and 3 (0.	-0.03 (-0.08, 0.03)
ndocrine 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 (2019) COV 101 Port 1, 2019 COV 1

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

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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)

Vaccine	DI I	
Vaccine	Placebo	Risk Difference
(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
95% CI)	95% CI)	(rate per 100 person-years,
N = 25282	N = 16433	95% CI)
1 (0.02)	0 (0.00)	0.01 (-0.01, 0.04)
1 (0.02)	0(00.0)	0.01 (-0.01, 0.04)
	and	
2 (0.03), (0.00, 0.11)	6 (0.15), (0.05, 0.32)	-0.12 (-0.25, 0.00)
1 (0.02)	(0.02)	-0.01 (-0.08, 0.05)
1 (0.02)	(0.07) 3 (0.07)	-0.06 (-0.16, 0.03)
0 (0.00)	2 (0.02)	-0.02 (-0.06, 0.02)
(00.0) 0	1 (0.02)	-0.02 (-0.06, 0.02)
SI,	risa	
, <sub>t</sub> h <sup>0</sup>		
alle		
ring		
	95% CI) N = 25282 1 (0.02) 1 (0.02)	95% CI) 95% CI) N = 25282 N = 16433  1 (0.02) 0 (0.00) 1 (0.02) 0 (0.00)  2 (0.03), (0.00, 0.11) 6 (0.15), (0.05, 0.32) 1 (0.02) 1 (0.02) 1 (0.02) 3 (0.07) 0 (0.00) 1 (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 (2019) COV 101 Port 1, 2019, CV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

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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)

			.2\\
·	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years, 95% CI)
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
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)	(00.0) 0	0.04 (-0.02, 0.10)
	0 (0 00) (0 00 0 11)	2 (2 22) (N.D. 272)	0.00 ( 0.01 .0.01)
kin 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)	(0.00)	0.01 (-0.01, 0.04)
Skin ulcer	1 (0.02)	0 (0.00), (NA, 0.09) 0 (0.00) 0 (0.00) 1 (0.02), (0.00, 0.14) 0 (0.00)	0.01 (-0.01, 0.04)
Survival and madical proceedings	2 (0.03) (0.00, 0.11)	3.eu .: 00 1 (0.00) (0.00, 0.14)	0.01 ( 0.07, 0.00)
urgical 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)
	outh)	NO TOTAL PROPERTY OF THE PROPE	
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	ark		

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 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 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)

	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n. rate per 100 person-years,	- (Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years, 95% CI)
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Coronary arterial stent insertion	1 (0.02)	0 (0.00)	0.01 (-0.01, 0.04)
Hip arthroplasty	0 (0.00)	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)	eu (6(0:00)	0.01 (-0.01, 0.04)
ocial circumstances	1 (0.02), (0.00, 0.09)	Uropa 38 (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)
Incoded	1 (0.02), (0.00, 0.09)	1 (0.02), (0.00, 0.14)	-0.01 (-0.06, 0.04)
	weting as	1 (0.02) 1 (0.02) 1 (0.00) 1 (0.00), (NA, 0.09) 0 (0.00) 1 (0.02), (0.00, 0.14)	
	Mark		

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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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo	oV-301/2019nCoV-302/2019nCoV-501  Immary of Event Rates of Serious Adverse Events	· ·	Confidential 35 of 35 ind of Follow-up) by Age
Table 20.1.1 Subgroup 30	(18-64 Ye		oriations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
CHOLECYSTITIS AND CHOLELITHIASIS	1 (0.02)	(00.0) 0	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)	(0.02)	-0.03 (-0.08, 0.03)
SARS-CoV-2 test positive	0 (0.00)	ouropa, applica (0.02)	-0.03 (-0.08, 0.03)
	ema.	2 (0.05), (0.00), 0.18)  Europa application application	

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).

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_1.rtf. Generated from t\_ser\_sum\_sub.sas 18JUL2021 20:59

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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)

	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	OEV CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	95% CI)
otal follow-up time (person-years)	1127.1	802.8	rtelle
verage follow-up time (days)	86.2	84.8	
Median follow-up time (days)	91	88 and any	
ny SAEs	76 (6.74), (5.31, 8.44)	99% CI) N = 3459 802.8 84.8 88 53 (6.60), (4.95, 8.64) 53 (6.60), (0.35, 1.80) 0 (0.00) 1 (0.12)	-0.67 (-3.04, 1.69)
ardiac 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)	(0.00) 0 dolor	0.14 (-0.05, 0.33)
Acute myocardial infarction	2 (0.18)	1 (0.12)	0.04 (-0.36, 0.43)
	autho!	•	
	atin <sup>9</sup> 2		

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 (2019) COV 101 Port 1, 2010, C. V. 101 Port 1, 2

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_2.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019 Table 28.1.2 Subgrou	9nCoV-301/2019nCoV-302/2019nCoV-501 up Summary of Event Rates of Serious Adverse Events	Page 2	. We
	(>= 65 Ye	ars)	riations
-	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	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)	eV (0.00)	0.11 (-0.11, 0.32)
Myocardial infarction	1 (0.09)	$20^{10.1} \times 10^{10.12}$	-0.08 (-0.41, 0.24)
Myocarditis	1 (0.09)	SULO 1 364 0 (0.00)	0.07 (-0.07, 0.21)
	ema. author	0 (0.00) 0 (0.00) 0 (0.00) 1 (0.12) 0 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 Table 28.1.2 Subgroup Summ	01/2019nCoV-302/2019nCoV-501 pary of Event Rates of Serious Adverse Events (>= 65 Year	Reported During the Study (from Day 0 to E	Confidential 3 of 17 nd of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
•	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	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)	2002. eu nica(0.12)	-0.15 (-0.45, 0.14)
Injury, poisoning and procedural complications	12 (1.06), (0.55, 1.86)	23 (0.37), (0.08, 1.09)	0.67 (-0.07, 1.40)
Femur fracture	2 (0.18) ema.	isation 0 (0.00)	0.14 (-0.05, 0.33)
	oting autho.	1 (0.12) and 1 (0.12) and 1 (0.12) and 2 (0.12) 2 (0.37), (0.08, 1.09) 0 (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 (2019) COV 101 Port 1, 2019 COV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_2.rtf. Generated from t\_ser\_sum\_sub\_sast 8JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019 Table 28.1.2 Subgrou	9nCoV-301/2019nCoV-302/2019nCoV-501 up Summary of Event Rates of Serious Adverse Events	Page 4	
	(>= 65 Ye	ars)	riations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	95% CI)
Cervical vertebral fracture	1 (0.09)	0(0.0)	0.11 (-0.11, 0.32)
Exposure to toxic agent	1 (0.09)	(00.0) (00.0)	0.07 (-0.07, 0.21)
Hip fracture	1 (0.09)	0 (0.00) 300	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)	(0.00)	0.11 (-0.11, 0.32)
Poisoning deliberate	1 (0.09)	$200^{24}$ $2010$ (0.00)	0.11 (-0.11, 0.32)
Radius fracture	1 (0.09)	SULO 1 364 0 (0.00)	0.11 (-0.11, 0.32)
	ema. author	europa.eu 0 (0.00) europa.eu 0 (0.00) 0 (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.

Table 28.1.2 Subgrou	up Summary of Event Rates of Serious Adverse Events (>= 65 Yea		Confidential 5 of 17 End of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	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 any	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)	opa.eu oplicato.12)	-0.11 (-0.33, 0.11)
Infections and infestations	11 (0.98), (0.49, 1.75)	74 (1.74), (0.95, 2.93)	-0.90 (-2.02, 0.22)
COVID-19	1 (0.09) 0 (0.00) 0 (0.00) 11 (0.98), (0.49, 1.75) 4 (0.35) ema.s	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 (2019) COV 101 Port 1, 2019, CV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_2.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/201 Table 28.1.2 Subgrou	19nCoV-301/2019nCoV-302/2019nCoV-501 up Summary of Event Rates of Serious Adverse Events	Page 6	
	(>= 65 Ye	ars)	riations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	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)	0 (0.00) 1 (0.12)	-0.08 (-0.41, 0.24)
Wound infection	1 (0.09)	2000 ap/10 (0.00)	0.11 (-0.11, 0.32)
Arthritis bacterial	0 (0.00)	2U1012 aPV 1 (0.12)	-0.15 (-0.45, 0.14)
	ema.	Europa, eu (0.00) 20012) 1 (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.

lovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301 Table 28.1.2 Subgroup Summar		Reported During the Study (from Day 0 to E	Confidential 7 of 17 nd of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
_	(n, rate per 100 person-years,	(n, rate per 100 person-years,	- (Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	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)		-0.15 (-0.45, 0.14)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (0.71), (0.31, 1.40)	0.62) (0.62) (0.20, 1.45)	0.09 (-0.61, 0.80)
Prostate cancer	3 (0.27)	2010 O (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)
	rketing author	1 (0.12) and	

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 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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Rep		Page 8	
	(>= 65 Ye	ars)	riations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	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)	3(0.12)	-0.11 (-0.33, 0.11)
Ovarian cancer	0 (0.00)	$20^{10.12}$	-0.11 (-0.33, 0.11)
Squamous cell carcinoma of the tongue	0 (0.00)	euro 2017 1 (0.12)	-0.11 (-0.33, 0.11)
	ema.	europa.eu 1 (0.12) europa.appli 1 (0.12) 1 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301, Table 28.1.2 Subgroup Summary		Page 9 Its Reported During the Study (from Day 0 to Er	. We
	(>= 65 Y		riations
	Vaccine	Placebo	Risk Difference
_	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	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)	(0.00)	0.07 (-0.07, 0.21)
Chest pain	0 (0.00)	$20^{10.1} \times 10^{10.12}$	-0.15 (-0.45, 0.14)
Oedema	0 (0.00)	eulo, apr 1 (0.12)	-0.15 (-0.45, 0.14)
	ema	Leuropa eu (0.00) Leuropa appli (0.12) 1 (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.

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-3 Table 28.1.2 Subgroup Summ	01/2019nCoV-302/2019nCoV-501 arry of Event Rates of Serious Adverse Events	9	Confidential 10 of 17 nd of Follow-up) by Age
· ·	(>= 65 Yea		riations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	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(0.0)	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) 2. 0 (0.00) 2. 0 (0.12)	0.07 (-0.07, 0.21)
Asthma	0 (0.00)	(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)	2 d (0.12)	-0.11 (-0.33, 0.11)
	ema.	europa.eu 0 (0.12) 1 (0.12) 1 (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 2019r File Name: t28\_1\_2.rtf. Generated from t\_ser\_sum\_sub.sas 18.00£2021 20:59 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)

			3/10
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	95% CI)
enal 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)
Jrinary retention	1 (0.09)	0 (0,00)	0.11 (-0.11, 0.32)
Renal failure	0 (0.00)	ODA, eu nica(0.12)	-0.15 (-0.45, 0.14)
scular disorders	4 (0.35), (0.10, 0.91)	ay (0.12), (0.00, 0.69)	0.17 (-0.18, 0.52)
Deep vein thrombosis	2 (0.18) ema	risation 0 (0.00)	0.14 (-0.05, 0.33)
	autho	0 (0.00) europa eu phica(0.12) (0.12), (0.00, 0.69) 0 (0.00)	
	ting		

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 (2019) COV 101 Port 1, 2019, CV 1

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_2.rtf. Generated from t\_ser\_sum\_sub-sas-18JUL2021 20:59

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 28.1.2 Subgroup Summa		Page 1 Reported During the Study (from Day 0 to En	Confidential 2 of 17 nd of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
-	(n, rate per 100 person-years,	(n, rate per 100 person-years,	- (Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	75% 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) and	-0.11 (-0.33, 0.11)
Musculoskeletal and connective tissue disorders Intervertebral disc protrusion	3 (0.27), (0.05, 0.78) 1 (0.09)	0 (0.00) (NA, 0.46) 0 (0.00)	0.21 (-0.03, 0.45) 0.07 (-0.07, 0.21)
Osteoarthritis Osteolysis	1 (0.09) 1 (0.09)	158tion apr 0 (0.00)	0.07 (-0.07, 0.21) 0.07 (-0.07, 0.21)
	3 (0.27), (0.05, 0.78) 1 (0.09) 1 (0.09) 1 (0.09) ema		

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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_2.rtf. Generated from t\_ser\_sum\_sub\_sast 8JUL2021 20:59

Table 28.1.2 Subgroup	Summary of Event Rates of Serious Adverse Events (>= 65 Yea		Confidential 3 of 17 d of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	95% CI)
ervous 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) and	0.07 (-0.07, 0.21)
astrointestinal 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, 0.10)
Gastrointestinal haemorrhage	1 (0.09)	0 (0.00)	0.07 (-0.07, 0.21)
Intestinal perforation	2 (0.18), (0.02, 0.64) 1 (0.09) 1 (0.09) 0 (0.00) ema.s	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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_2.rtf. Generated from t\_ser\_sum\_sub\_sast 8JUL2021 20:59

Table 28.1.2 Subgroup S	ummary of Event Rates of Serious Adverse Events (>= 65 Yea	Reported During the Study (from Day 0 to En	Confidential 4 of 17 Id of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	rate per 100 person-years, 95% CI)
Nausea	0 (0.00)		-0.15 (-0.45, 0.14)
Obstructive pancreatitis	0 (0.00)	1 (0.12) 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) a	-0.15 (-0.45, 0.14)
ar and labyrinth disorders	1 (0.09), (0.00, 0.49)	Q(0.00), (NA, 0.46)	0.08 (-0.07, 0.23)
Vertigo	1 (0.09)	puron app 0 (0.00)	0.08 (-0.07, 0.23)
Metabolism and nutrition disorders	0 (0.00) 1 (0.09), (0.00, 0.49) 1 (0.09) 1 (0.09), (0.00, 0.49) ema.s	1 (0.12), (0.00, 0.69)	-0.00 (-0.31, 0.30)

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 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

Table 28.1.2 Subgroup Sum	nmary of Event Rates of Serious Adverse Events (>= 65 Yea		Confidential 15 of 17 nd of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	95% CI)
Dehydration	1 (0.09)	0(00.0)	0.11 (-0.11, 0.32)
Hypoalbuminaemia	0 (0.00)	1 (0.12)	-0.11 (-0.33, 0.11)
eproductive 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)	(0.00)	0.11 (-0.11, 0.32)
Benign prostatic hyperplasia	0 (0.00)	uropa applica (0.12)	-0.15 (-0.45, 0.14)
kin 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) ellion	1 (0.12), (0.00, 0.69) 1 (0.12), (0.00, 0.69) 1 (0.12) 1 (0.12) 0 (0.00), (NA, 0.46) 0 (0.00)	0.07 (-0.07, 0.21)

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 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

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCo Table 28.1.2 Subgroup Տև	oV-301/2019nCoV-302/2019nCoV-501 Immary of Event Rates of Serious Adverse Events (>= 65 Yea	Reported During the Study (from Day 0 to E	Confidential 16 of 17 Ind of Follow-up) by Age
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776	N = 3459	(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) and	-0.11 (-0.33, 0.11)
Hepatobiliary disorders	0 (0.00), (NA, 0.33)	(0.12) (0.00, 0.69)	-0.11 (-0.33, 0.11)
Liver injury	0 (0.00)	uropa appli (0.12)	-0.11 (-0.33, 0.11)
nvestigations	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) elli	1 (0.12)	-0.11 (-0.33, 0.11)
	0 (0.00), (NA, 0.33) 0 (0.00) 0 (0.00), (NA, 0.33) 0 (0.00) ema.		

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 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

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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)

Vaccine	Placebo	_ Risk Difference
(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
95% CI)	95% CI)	(rate per 100 person-years,
N = 4776	N = 3459	95% CI)
0 (0.00), (NA, 0.33)	2 (0.25), (0.03, 0.90)	-0.30 (-0.72, 0.12)
0 (0.00)	1 (0.12)	-0.15 (-0.45, 0.14)
0 (0.00)	1 (0.12) and	-0.15 (-0.45, 0.14)
0 (0.00), (NA, 0.33)	(0.12) (0.00, 0.69)	-0.15 (-0.45, 0.14)
0 (0.00)	1000 300 (0.12)	-0.15 (-0.45, 0.14)
·ma.	ed ation of	
	(n, rate per 100 person-years, 95% CI) N = 4776 0 (0.00), (NA, 0.33) 0 (0.00) 0 (0.00)	(n, rate per 100 person-years, 95% CI) 95% CI)  N = 4776 N = 3459  0 (0.00), (NA, 0.33) 2 (0.25), (0.03, 0.90) 0 (0.00) 1 (0.12) 0 (0.00), (NA, 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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019r File Name: t28\_1\_2.rtf. Generated from t\_ser\_sum\_sub.sas 18JUI 2021 20:59

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N 14422	(0/ OE0/ 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)		-0.01 (-0.04, 0.01)
Cardiac arrest	2 (<0.01)	3 (0.02)	-0.01 (-0.04, 0.01)
Infections and infestations COVID-19 pneumonia	2 (<0.01), (0.00, 0.03)	2 (0.01), (0.00, 0.04) (0.00)	-0.00 (-0.02, 0.02) 0.01 (-0.00, 0.02)
Septic shock	1 (<0.01)	100 (0.00)	0.00 (-0.00, 0.01)
COVID-19	0 (0.00)	a.e. 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)
	a lith	70.	
	ring ac		
	orker.		

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

Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 31 1 1 a Sub		Cont Page 2 of 2 During the Study (from Day 0 to End of Follow-up)	
Tuble 01.1.1.4 oub	(18-64 Ye		
_	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 25282	N = 16433	(%, 95% CI)
Sudden death	1 (<0.01)	(n, %, 95% CI) N = 16433 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) and	0.00 (-0.00, 0.01)
Vascular disorders	1 (<0.01), (0.00, 0.02)	e v (0.00) (0.00, 0.02)	0.00 (-0.00, 0.01)
Circulatory collapse	1 (<0.01)	Tropa, applico (0.00)	0.00 (-0.00, 0.01)
	ema.	europa el (0.00) (0.00, 0.02) europa appli o (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.

File Name: t31\_1\_1\_a.rtf. Generated from t\_death\_soc\_sub.sas 29JUL2021 18:33

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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## 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)

			410.
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)	(n, %, 95% CI)	(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Any unsolicited AEs	5 (0.10), (0.03, 0.24)	N = 3459 3 (0.09), (0.02, 0.25) 1 (0.03), (0.00, 0.16)	0.03 (-0.11, 0.16)
		yte.	, · ·
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)
		ion a	
General disorders and administration site conditions	1 (0.02), (0.00, 0.12)	<b>(0.00)</b> (0.00, 0.11)	0.03 (-0.02, 0.08)
Death	1 (0.02)	ema.europa.ev (0.00) (0.00, 0.11)  ema.europa.appli 0 (0.00)  2 (0.06), (0.01, 0.21)  1 (0.03)	0.03 (-0.02, 0.08)
		eur ap	
nfections 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)	er, orisa 1 (0.03)	0.00 (-0.07, 0.07)
		itho	
	20	200	
	Leting		
	arke		

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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019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301. <b>Table 31.1.2.a Subgr</b>		Page 2 of Ouring the Study (from Day 0 to End of Follow-up) ars)	
	Vaccine	Placebo	Risk Difference
System Organ Class	(n, %, 95% CI)		(Vaccine - Placebo)
Preferred Term (# of Subjects)	N = 4776	N = 3459	(%, 95% CI)
Bacterial sepsis	0 (0.00)	1 (0.03)	(%, 95% CI) -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) any	0.03 (-0.02, 0.08)
Poisoning deliberate	1 (0.02)	0 (0.00) and	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)	1000 300/10 (0.00)	0.02 (-0.02, 0.05)
	ma.	Europa el (0.00) (0.00) Europa appli 0 (0.00)	
	el, or	isac	

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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2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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## 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

	Vaccine	Placebo	Risk Difference
_	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	(Vaccine - Placebo) (rate per 100 person-years, 95% Cl)
Total follow-up time (person-years)	7465.0	4877.1	rtelle
Average follow-up time (days)	90.7	89.6	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Median follow-up time (days)	92	4877.1 89.6 91	
		and	
Any PIMMCs	27 (0.36), (0.24, 0.53)	9 (0.18), (0.08, 0.35)	0.16 (-0.02, 0.34)
		a.eu licatio	
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)	(0.00)	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)
		'tho'	
	2 3	Ac.	
	ting	91 91 ey (0.18), (0.08, 0.35) ey (0.18), (0.08, 0.35) 0 (0.00, 0.15) 0 (0.00) 1 (0.02) 0 (0.00)	
	erkec.		

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 individual group statistics are not adjusted by strata.

Table 32 Summary of Event	Rates of Potential Immune-Mediated Medical Co Per Site Rep		Confidential 2 of 5 Day 0 to End of Follow-up)
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	(rate per 100 person-years, 95% CI)
Rheumatoid arthritis	1 (0.01)	1 (0.02)	-0.00 (-0.05, 0.05)
lervous 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)	(0.02)	-0.01 (-0.06, 0.04)
Neuralgia	1 (0.01)	2000000000000000000000000000000000000	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 (0.01) 1 (0.01) 1 (0.01) 1 (0.01) 1 (0.01) 2 ema. (	1 (0.02)	-0.01 (-0.06, 0.04)

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 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 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

	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years, 95% CI)
Preferred Term (# of Events)	N = 30058	N = 19892	95% CI)
Multiple sclerosis	0 (0.00)	1 (0.02)	-0.02 (-0.07, 0.02)
		4 BULY	
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)	(0.00)	0.01 (-0.01, 0.03)
Hyperthyroidism	1 (0.01)	20/10 (0.00)	0.01 (-0.01, 0.03)
	e e	Sylvan Shi	
ye 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)
	2 (0.03) 1 (0.01) 1 (0.01) 4 (0.05), (0.01, 0.14) 3 (0.04) 1 (0.01) 2 marketing authoric		

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 32 Summary of Event	t Rates of Potential Immune-Mediated Medical C Per Site Rep	onditions Reported During the Study (from Day 0 oorted	to End of Follow-up)
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
stem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	95% CI) N = 19892	95% CI)
in 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 (0,92)	-0.02 (-0.07, 0.02)
ichenoid keratosis	0 (0.00)	202. eu nica(0.02)	-0.02 (-0.07, 0.02)
ood and lymphatic system disorders	1 (0.01), (0.00, 0.07)	al (0.02), (0.00, 0.11)	-0.01 (-0.05, 0.03)
Thrombocytopenia	1 (0.01) ema.	0 (0.00) 1 (0.02) 1 (0.02) 2 (0.02), (0.00, 0.11) 1 (0.02) 0 (0.00), (NA, 0.08)	-0.01 (-0.05, 0.03)
irdiac disorders	1 (0.01), (0.00, 0.07) author	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).

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Table 32 Summary of Event Rat	tes of Potential Immune-Mediated Medical Co Per Site Rep		Confidential e 5 of 5 Day 0 to End of Follow-up)  Plantations
	Vaccine	Placebo	Risk Difference
•	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	95% CI)
Myocarditis	1 (0.01)	0 (0.00)	0.02 (-0.02, 0.05)
Sastrointestinal disorders	1 (0.01), (0.00, 0.07)	(n, rate per 100 person-years, 95% CI)  N = 19892  0 (0.00)  1 (0.02), (0.00, 0.11)  0 (0.00)	-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)	7 (0:02)	-0.02 (-0.05, 0.02)
niury poisoning and procedural complications	1 (0.01) (0.00, 0.07)	110P2 3P0(100) (NA 0.08)	0.02 (-0.02, 0.05)
Colitis ulcerative Crohn's disease  njury, poisoning and procedural complications Chillblains  nvestigations Heparin-induced thrombocytopenia test  ote: Risk difference and its Confidence Intervals (CIs) a dividual group statistics are not adjusted by strata	1 (0.01)	0 (0.00)	0.02 (-0.02, 0.05)
nvestigations	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)
	rketille		
	Mar		
	301		
ato. Dick difference and its Confidence Intervals (Cls) a	providency to different Mantal Haanszal Standardi	zod Dick Estimatos and OEV normal confido	neo limits with the stratification by study, whi
dividual group statistics are not adjusted by strate.	ne computed from Mariter-Haeriszer Standardi	zeu Risk Estillates allu 45% Holfflal Collide	rice illinits with the stratification by study, will
		19nCoV-301 and 2019nCoV-302).	
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2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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#### 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

	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	
System Organ Class	2=2/ 21	0=0.00	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	(Vaccine - Placebo) (Fate per 100 person-years, 95% CI)
Total follow-up time (person-years)	7465.0	4877.1	telle
Average follow-up time (days)	90.7	89.6	
Median follow-up time (days)	92	95% CI) N = 19892 4877.1 89.6 91 19 (0.39), (0.23, 0.61) 7 (0.14), (0.06, 0.30) 3 (0.06) 2 (0.04) 1 (0.02)	
		and	
Any PIMMCs	30 (0.40), (0.27, 0.57)	19 (0.39), (0.23, 0.61)	-0.04 (-0.27, 0.19)
	0 (0 40) (0 0 ( 0 00)	odied diedicación	0.05 ( 0.40, 0.00)
Nervous system disorders	9 (0.12), (0.06, 0.23)	(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)
	14.	70,	
	alle		
	ring		
	arker		

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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19nCoV-101 Part1/2019nCoV-101 Part2/2019nCo  Table 37 Summary of Event	oV-301/2019nCoV-302/2019nCoV-501 : Rates of Potential Immune-Mediated Medical Co Per Protocol Defir		
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	95% CI)
Narcolepsy	1 (0.01)	(00.0) 0	0.01 (-0.01, 0.03)
Multiple sclerosis	0 (0.00)	1 (0.02)	-0.02 (-0.07, 0.02)
kin 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)	eV (0.00)	0.02 (-0.01, 0.05)
Psoriasis	2 (0.03)	(0.00) 0 (0.00)	0.02 (-0.01, 0.05)
Erythema nodosum	1 (0.01)	O(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)
	6 (0.08), (0.03, 0.17) 2 (0.03) 2 (0.03) 1 (0.01) 1 (0.01) 0 (0.00)  arketing author		

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 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

019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 37 Summary of Event Rate		Page Conditions Reported During the Study (from Ened Criteria	
	Vaccine	Placebo	Risk Difference
_	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	75% 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 (0,20)	0.02 (-0.02, 0.05)
Arthritis reactive	0 (0.00)	002.eu 01/ca(0.02)	-0.02 (-0.05, 0.02)
ndocrine disorders	3 (0.04), (0.01, 0.12)	ay (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) ell'hor	1 (0.02)	-0.01 (-0.06, 0.04)
	arketing au	3 (0.06) and 0 (0.00) and 0 (0.00) and 0 (0.00) and 0 (0.00) and 0 (0.02) (0.00, 0.11) 0 (0.00) 1 (0.02)	

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 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.

## 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

Table 37 Summary of Event	Rates of Potential Immune-Iviediated Iviedical C Per Protocol Defi	Conditions Reported During the Study (from Day Cined Criteria	ofidential 4 O to End of Follow-up) Criations
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
iystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	95% CI)
ye 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)
lood 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)	1 (0.02)  2 (0.04), (0.00, 0.15)  2 (0.04), (0.00, 0.15)  0 (0.00)  1 (0.02)  1 (0.02)	-0.01 (-0.08, 0.06)
astrointestinal disorders	2 (0.03), (0.00, 0.10)	al (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)
	ing ac		

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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2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

## Confidential Page 1 of 6

## 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

	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	050/ 01)	95% CI)	(vaccine - Piacebo) (rate per 100 person-years, 95% CI)
Preferred Term (# of Events)	N = 30058	N = 19892	95% CI)
Total follow-up time (person-years)	7465.0	4877.1	rtelli
Average follow-up time (days)	90.7	89.6	
Median follow-up time (days)	92	95% CI) N = 19892  4877.1 89.6 91  21 (0.43), (0.27, 0.66)  8 (0.16), (0.07, 0.32) 3 (0.06) 2 (0.04) 0 (0.00)	
		and	
Any PIMMCs	41 (0.55), (0.39, 0.75)	21 (0.43), (0.27, 0.66)	0.06 (-0.20, 0.31)
		a eu licatio	
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)
	.+40		
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	orket.		

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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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 Table 42 Summary of Event Rate		Page 2 onditions Reported During the Study (from D	
	Vaccine	Placebo	Risk Difference
_	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	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)	(0.00)	0.01 (-0.01, 0.03)
Multiple sclerosis	0 (0.00)	auropa, applici (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) ellipor	0 (0.00)	0.03 (-0.01, 0.07)
	arketing auti.	0 (0.00) and 0 (0.00) and 0 (0.00) and 0 (0.00) and 0 (0.00) application application 5 (0.10), (0.03, 0.24) 0 (0.00)	

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 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

ovavax, Inc 019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501 Table 42 Summary of Event Rates of Potential Immune-Mediated Medical Conc		onditions Reported During the Study (from I	Confidential 3 of 6  Day 0 to End of Follow-up)
	Per Site Reported or Proto	ocor Defined Criteria	oriatio.
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	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 (0.92)	-0.02 (-0.05, 0.02)
kin 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)
	0 (0.00) 6 (0.08), (0.03, 0.17) 2 (0.03) 2 (0.03) 1 (0.01) 2 (0.04)		

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 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

	Per Site Reported or Proto	col Defined Criteria	nfidential 6 0 to End of Follow-up)
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
rstem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	95% CI) N = 19892 0 (0.00)	95% CI)
Pemphigoid	1 (0.01)	0 (0.00)	0.02 (-0.02, 0.05)
Lichen planus	0 (0.00)	0 (0.00) 1 (0.02)	-0.02 (-0.07, 0.02)
Lichenoid keratosis	0 (0.00)	1 (0.02) and	-0.02 (-0.07, 0.02)
docrine disorders	4 (0.05), (0.01, 0.14)	(0.02) (0.00, 0.11)	0.02 (-0.04, 0.09)
Basedow's disease	2 (0.03)	(0.00) DONO (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)	1 (0.02), (0.00, 0.11) 1 (0.02) 1 (0.00) 1 (0.00) 1 (0.02), (0.00, 0.11)	0.01 (-0.01, 0.03)
e disorders	4 (0.05), (0.01, 0.14) author	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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	Per Site Reported or Pro	otocol Defined Criteria	onfidential of 6 y 0 to End of Follow-up)
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
tem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
referred Term (# of Events)	N = 30058	N = 19892	(rate per 100 person-years, 95% CI) 0.01 (-0.05, 0.07)
veitis	3 (0.04)	1 (0.02)	0.01 (-0.05, 0.07)
idocyclitis	1 (0.01)		
od and lymphatic system disorders	2 (0.03), (0.00, 0.10)	2 (0.04), (0.00, 0.15)	-0.01 (-0.08, 0.06)
hrombocytopenia	2 (0.03)	0 (0.00) 2 (0.04), (0.00, 0.15) 2 (0.04), (0.00, 0.15) 0 (0.00) 1 (0.02) 1 (0.02)	-0.01 (-0.08, 0.06)
strointestinal disorders	2 (0.03), (0.00, 0.10)	22 (0.04), (0.00, 0.15)	-0.02 (-0.08, 0.05)
olitis ulcerative	1 (0.01)	0 (0.00)	0.01 (-0.01, 0.03)
rohn's disease	1 (0.01)	1 (0.02)	-0.01 (-0.05, 0.03)
oeliac 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).

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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-30 <b>Table 42 Summary of Event Rat</b>	01/2019nCoV-302/2019nCoV-501 es of Potential Immune-Mediated Medical Co Per Site Reported or Proto	onditions Reported During the Study (from I	Confidential 6 of 6 Day 0 to End of Follow-up)
	Vaccine	Placebo	Risk Difference
•	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 30058	N = 19892	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 (00.0)	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)	03.EU 11C8 (0:00)	0.02 (-0.02, 0.05)
Investigations	1 (0.01), (0.00, 0.07)	30 (0.00), (NA, 0.08)	0.01 (-0.01, 0.03)
Heparin-induced thrombocytopenia test	1 (0.01) ema.	15ation 0 (0.00)	0.01 (-0.01, 0.03)
	oting author	0 (0.00) (0.00), (NA, 0.08) (0.00) (0.00), (NA, 0.08) 0 (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.

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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). MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019 File Name: t42.rtf. Generated from t\_pimmc\_sum\_sub.sas 19JUL2021 12:55

2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

			.3/10
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo) (rate per 100 person-years, 95% CI)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Total follow-up time (person-years)	6337.9	4074.4	) <del>-</del>
Average follow-up time (days)	91.6		
Median follow-up time (days)	93	4074.4 90.6 92 and any	
Any PIMMCs	91.6 93 36 (0.57), (0.40, 0.79) 12 (0.19), (0.10, 0.33) 4 (0.06) 3 (0.05) 1 (0.02) s) are computed from Mantel-Haenszel Standardia	C 16 (0.39), (0.22, 0.64)	0.11 (-0.17, 0.39)
Nervous system disorders	12 (0.19), (0.10, 0.33)	28 (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)
	4 304		
		zed Risk Estimates and 95% normal confidence	ce limits with the stratification by study, wh
ndividual group statistics are not adjusted by strata.			
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	(from Day 0 to End of Follow-up) Per Site Repo (18-64 Yea		nfidential f 6 ng the Study
	Vaccine	Placebo	Risk Difference (Vaccine - Placebo) (rate per 100 person-years, 95% CI)
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Facial paralysis	1 (0.02)	1 (0.02)	-0.00 (-0.06, 0.06)
Hypoaesthesia	1 (0.02)	1 (0.02) and	-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)	(9.00)	0.01 (-0.01, 0.04)
Multiple sclerosis	0 (0.00)	110Pa 3PP11 1 (0.02)	-0.03 (-0.08, 0.03)
kin 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)
	1 (0.02) 1 (0.02) 1 (0.02) 1 (0.02) 1 (0.02) 0 (0.00) 6 (0.09), (0.03, 0.21) 2 (0.03) 2 (0.03) 2 (0.03) arketing authori		
	Ma Ma		
te: Risk difference and its Confidence Intervals (CIs)	A SILL		
te: Risk difference and its Confidence Intervals (CIs) lividual group statistics are not adjusted by strata.	) are computed from Mantel-Haenszel Standardiz	zed Risk Estimates and 95% normal confidence I	imits with the stratification by study, whil
edDRA version: 23.0 (2019nCoV-101 Part 1, 2019nC	by 101 Part 2, and 2010nCoV E01) and 22.1 (201	10nCoV 201 and 2010nCoV 202)	
- ( \	00-101 Part 2, and 201911007-501) and 25.1 (20)	1911CUV-301 and 201911CUV-302).	
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• .	01/2019nCoV-302/2019nCoV-501 o Summary of Event Rates of Potential Immu rom Day 0 to End of Follow-up) Per Site Repo (18-64 Ye	ne-Mediated Medical Conditions Reported or Protocol Defined Criteria by Age	Confidential 3 of 6 During the Study
	Vaccine	Placebo	Risk Difference (Vaccine - Placebo) (rate per 100 person-years, 95% CI)
<del>-</del>	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Erythema nodosum	1 (0.02)	0(0.0)	0.01 (-0.01, 0.04)
Pemphigoid	1 (0.02)	0 (0.00) and	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)	1002 eu 100 (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)
	1 (0.02) 0 (0.00) 0 (0.00) 5 (0.08), (0.03, 0.18) 2 (0.03) 1 (0.02) 1 (0.02) 2 (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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	/2019nCoV-301/2019nCoV-302/2019nCoV-501 .1.1 Subgroup Summary of Event Rates of Potential Immune (from Day 0 to End of Follow-up) Per Site Report (18-64 Year	Page 4 e-Mediated Medical Conditions Reported D ted or Protocol Defined Criteria by Age	
-	Vaccine	Placebo	Risk Difference (Vaccine - Placebo) (rate per 100 person-years, 95% CI)
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Rheumatoid arthritis	1 (0.02)	2 (0.05)	-0.04 (-0.13, 0.04)
Arthritis reactive	0 (0.00)	1 (0.02) and	-0.02 (-0.06, 0.02)
Eye disorders Uveitis Iridocyclitis	4 (0.06), (0.02, 0.16) 3 (0.05) 1 (0.02) 3 (0.05), (0.01, 0.14) ema.el 1 (0.02) 1 (0.02) 1 (0.02) marketing authoris	1000 apply 1 (0.02) (0.00, 0.14) (0.02) (0.00)	0.03 (-0.05, 0.10) 0.01 (-0.06, 0.08) 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) all	0 (0.00)	0.01 (-0.01, 0.04)
	Tany markee.		

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 strate.

INIEQUKA Version: 23.0 (2019nCoV-101 Part 1,2019nCoV-101 Part 2, and 2019nCoV File Name: t46\_1\_1.rtf. Generated from \_pimmc\_sum\_sub.sas 19JUL2021 12:55 MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

	(18-64 Yea	,	nfidential f 6 ing the Study
	Vaccine	Placebo	Risk Difference
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
ystem Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	95% CI)
Hyperthyroidism	1 (0.02)	0 (0.00)	0.01 (-0.01, 0.04)
ood 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)	(8.02)	0.01 (-0.07, 0.08)
	_ (=:==,	Coby. Dolice	( , ,
ardiac 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)
astrointestinal disorders	N = 25282 1 (0.02) 2 (0.03), (0.00, 0.11) 2 (0.03) 1 (0.02), (0.00, 0.09) 1 (0.02) 1 (0.02), (0.00, 0.09) 1 (0.02) 0 (0.00)  Thank any  Cls are computed from Mantel-Haenszel Standardi: a.	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) +109	1 (0.02)	-0.03 (-0.08, 0.03)
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te: Risk difference and its Confidence Intervals (@	(IS) are computed from Mantel-Haenszel Standardi	zed Risk Estimates and 95% normal confidence I	imits with the stratification by study, wh
ividual group statistics are not adjusted by soata	a.		3.
		19nCoV-301 and 2019nCoV-302).	
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•	o Summary of Event Rates of Potential Immu rom Day 0 to End of Follow-up) Per Site Repo	ne-Mediated Medical Conditions Reported I orted or Protocol Defined Criteria by Age	Confidential 6 of 6 Ouring the Study
	(18-64 Yea	ars)	" Naric
	Vaccine	Placebo	Dick Difference
•	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo) (rate per 100 person-years, 95% CI)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 25282	N = 16433	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) 200	0.02 (-0.02, 0.06)
		oil which	
Investigations	1 (0.02), (0.00, 0.09)	0 (0.90), (NA, 0.09)	0.01 (-0.01, 0.04)
Heparin-induced thrombocytopenia test	1 (0.02)	1000 000 (0.00)	0.01 (-0.01, 0.04)
	ema.e	europa, et b (0.00) (100)  Europa appli 0 (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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2019nCoV-101 Part1/2019nCoV-101 Part2/2019nCoV-301/2019nCoV-302/2019nCoV-501

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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)

Vaccine (n, rate per 100 person-years, 95% CI)	Placebo (n, rate per 100 person-years,	Risk Difference
· · · · · · · · · · · · · · · · · · ·	(n, rate per 100 person-years,	( Vaccino Dlacobo)
95% CI)		(Vaccine - Placebo)
7570 01)	95% CI)	(rate per 100 person-years,
N = 4776	N = 3459	(rate per 100 person-years, 95% CI)
1127.1	802.8	27
86.2	84.8	
91	88 and	
5 (0.44), (0.14, 1.04)	5 (0.62) (0.20, 1.45)	-0.24 (-0.90, 0.42)
	rope applie	
2 (0.18), (0.02, 0.64)	2 (0.25), (0.03, 0.90)	-0.04 (-0.44, 0.36)
1 (0.09)	1 (0.12)	-0.04 (-0.30, 0.22)
1 (0.09)	1 (0.12)	-0.00 (-0.31, 0.30)
itho		
1 (0.09), (0.00, 0.49)	0 (0.00), (NA, 0.46)	0.07 (-0.07, 0.21)
narketing		
- N (1.		
	1127.1 86.2 91 5 (0.44), (0.14, 1.04) 2 (0.18), (0.02, 0.64) 1 (0.09) 1 (0.09)	1127.1 802.8 86.2 84.8 91 88 and 5 (0.44), (0.14, 1.04)

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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Novavax, Inc 2019nCoV-101 Part1/2019nCoV-101 Part2/2019nC <b>Table 46.1.2 Sub</b>	oV-301/2019nCoV-302/2019nCoV-501 group Summary of Event Rates of Potential Immur (from Day 0 to End of Follow-up) Per Site Report (>= 65 Yea	Page 2 c ne-Mediated Medical Conditions Reported Du rted or Protocol Defined Criteria by Age	
	·	,	Or No.
	Vaccine	Placebo	Risk Difference (Vaccine - Placebo) (rate per 100 person-years, 95% CI)
	(n, rate per 100 person-years,	(n, rate per 100 person-years,	(Vaccine - Placebo)
System Organ Class	95% CI)	95% CI)	(rate per 100 person-years,
Preferred Term (# of Events)	N = 4776		
Basedow's disease	1 (0.09)	0 (0.00) and all 1	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) (NA, 0.46) 0 (0.00) 2 (0.25), (0.03, 0.90) 0 (0.00) 2 (0.25) 1 (0.12), (0.00, 0.69)	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) emori	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) eting	1 (0.12)	-0.11 (-0.33, 0.11)
	0 (0.00), (NA, 0.33) 0 (0.00) eting authorized marketing		

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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