# STATISTICAL ANALYSIS PLAN

# Phase 2: Final Analysis

# for

# COVIVAC Phase 1/2 Protocol

# Version 3.0 dated 27 Sep 2021

**Study Title:**
**A Phase 1/2 Randomized, Placebo-controlled (phase 1) and Active-controlled (phase 2), Observer-blind Trial to Assess the Safety and Immunogenicity of COVIVAC Vaccine Produced by IVAC in Adults 18-59 and ≥ 60 years old in Vietnam**

**Sponsored by**
Institute of Vaccines and Medical Biologicals (IVAC)

**Prepared and Distributed by:**
Center of Excellence for Biomedical and Public Health Informatics (BIOPHICS), Bangkok, Thailand

**Version 1.0**
**25 October 2022**

| | |
|---|---|
| **Protocol Number Code:** | COVIVAC Phase 1/2 |
| **Development Phase:** | Phase 1/2 |
| **Products:** | **Investigational Vaccine:**<br>Inactivated Newcastle Disease Virus (NDV) chimera expressing a trimeric pre-fusion form of the SARS-CoV-2 Spike (S) protein that contains six proline mutations (HexaPro, HXP); for intramuscular (IM) administration. One formulation of COVIVAC evaluated in this study (Phase 1) includes 1.5 mg of the adjuvant CpG 1018 (a 22-mer phosphorothioate-linked oligodeoxynucleotide).<br><br>**Control product of Phase 1:**<br>Placebo: Phosphase-buffered saline (PBS); for IM administration<br><br>**Control product of Phase 2:**<br>Authorized Covid-19 vaccine: Astrazeneca AZD1222 |
| **Form/Route:** | Intramuscular |
| **Sponsor:** | Institute of Vaccines and Medical Biologicals (IVAC)<br>No. 9, Pasteur Street, Nha Trang City, Khanh Hoa Province, Vietnam |
| **Date of the Analysis Plan:** | 25 Oct 2022 |
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This study was performed in compliance with Good Clinical Practice.



# COVIVAC Phase 1/2 STATISTICAL ANALYSIS PLAN PHASE 2 – FINAL ANALYSIS

## REVISION HISTORY

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PROTOCOL TITLE:

A Phase 1/2 Randomized, Placebo-controlled (phase 1) and Active- controlled (phase 2), Observer-blind Trial to Assess the Safety and Immunogenicity of COVIVAC Vaccine Produced by IVAC in Adults 18-59 and ≥ 60 years old in Vietnam

PROTOCOL NUMBER: COVIVAC Phase 1/2

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# TABLE OF CONTENTS

## List of Tables

See Appendix 1

## List of Figure

See Appendix 2

## List of Listing

See Appendix 3

# LIST OF ABBREVIATIONS

| | |
|---|---|
| Ab | Antibody |
| ACE2 | Angiotensin-converting enzyme 2 |
| ADCC | Antibody-dependent cellular cytotoxicity |
| ADE | Antibody-dependent enhancement |
| ADR | Adverse drug reaction |
| AE | Adverse event |
| AESI | Adverse event of special interest |
| ALT | Alanine transaminase |
| ANCA | Anti-neutrophil cytoplasmic antibody |
| ARDS | Acute respiratory distress syndrome |
| AST | Aspartate transaminase |
| ATC | Anatomical Therapeutic Chemical |
| BAU | Binding Antibody Units |
| BIOPHICS | Center of Excellence for Biomedical and Public Health Informatics |
| BMI | Body Mass Index |
| BPL | Beta-propiolactone |
| C | Celsius |
| CAPA | Corrective action and preventive action |
| CBER | Center for Biologics Evaluation and Research |
| CDC | Centers for Disease Control and Prevention |
| CI | Confidence interval |
| Cm | Centimeter |
| CMI | Cell-mediated immunity |
| COVID-19 | Coronavirus disease 2019 (disease caused by SARS-CoV-2) |
| CREST | Calcinosis, Raynaud's phenomenon, esophageal dysmotility, sclerodactyly, and telangiectasia |
| CRF | Case Report Form |
| CRO | Contract Research Organization |
| CSR | Clinical Study Report |
| D | day(s) |
| DSMB | Data and Safety Monitoring Board |
| EC | Ethics Committee |
| EDC | Electronic Data Capture |
| ELISA | Enzyme-linked Immunosorbent Assay |
| ELISpot | Enzyme-linked Immunospot |
| ELU | ELISA Units |
| EOS | End of study |
| ER | Emergency Room |
| EUA | Emergency Use Authorization |
| F | Fahrenheit |
| FDA | US Food and Drug Administration |
| FIPV | Feline infectious peritonitis virus |
| G | Group |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practice |

## LIST OF ABBREVIATIONS (CONTINUE)

| | |
|---|---|
| GMC | Geometric mean concentration |
| GMFR | Geometric mean fold rise |
| GMP | Good Manufacturing Practice |
| GMT | Geometric mean titer |
| HBsAg | Hepatitis B surface antigen |
| hCG | Serum human gonadotrophic hormone |
| HCV Ab | Hepatitis C virus antibody |
| Hgb | Gemoglobin |
| HIV 1/2 Ab | Human immunodeficiency virus 1 and 2 antibody |
| HN | Hemagglutinin-neuraminidase |
| HXP | HexaPro |
| IATA | International Air Transport Association |
| IB | Investigator's Brochure |
| ICF | Informed consent form |
| ICH | International Conference on Harmonisation |
| ID | Identification |
| IIV | Inactivated influenza virus vaccine |
| IgG | Immunoglobulin G |
| IL | Interleukin |
| IM | Intramuscular |
| IME | Important medical event |
| IN | Intranasal |
| INF | Interferon |
| IP | Investigational product |
| IRB | Institutional Review Board |
| ISMMS | Icahn School of Medicine at Mount Sinai |
| ISO | Internaitonal Organization for Standardization |
| IP | Investigational product |
| ISMMS | Icahn School of Medicine at Mount Sinai |
| IV | Intravenous |
| IVAC | Institute of Vaccines and Medical Biologicals |
| LLN | Lower limit of normal range |
| LLOQ | Lower limit of quantification |
| LMIC | Low- and middle-income country |
| LSLV | Last subject last visit |
| MAAE | Medically-attended adverse event |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MERS-CoV | Middle East respiratory syndrome coronavirus |
| MIS-C | Multisystem inflammatory syndrome in children |
| mm | Millimeter |
| ml | Milliliter |
| MoH | Ministry of Health |
| N | Nucleocapsid |
| NAb | Neutralizing antibody |
| NDV | Newcastle disease virus |
| NICVB | National Institute for Control of Vaccines and Biological |
| NIHE | National Institute of Hygiene and Epidemiology |
| $NT_{50}$ | 50% neutralizing antibody titer |

## LIST OF ABBREVIATIONS (CONTINUE)

| | |
|---|---|
| NTF | Note to file |
| PBMC | Peripheral blood mononuclear cell |
| PBS | Phosphate-buffered saline |
| PE | Physical examination |
| PI | Principal investigator (the term is used throughout to indicate PI or designee) |
| PIMMC | Potential immune-mediated medical conditions |
| Plt | Platelet |
| PNA | Pseudovirus Neutralization Assay |
| PPE | Personal protective equipment |
| PP IMM | Per protocol immunogenicity population |
| PSRT | Protocol Safety Review Team |
| PT | Preferred Term |
| qPCR | Quantitative polymerase chain reaction |
| R | Recovery |
| $R_0$ | Reproduction number |
| RLU | Relative luminescence units |
| RNA | Ribonucleic acid |
| RSV | Respiratory syncytial virus |
| RT-PCR | Reverse transcription polymerase chain reaction |
| S | Spike |
| SAE | Serious adverse event |
| SAP | Statistical Analysis Plan |
| SARS-CoV | Severe acute respiratory syndrome coronavirus |
| SARS-CoV-2 | Severe acute respiratory syndrome coronavirus 2 |
| SC | Subcutaneous |
| SOC | System Organ Class |
| SOP | Standard Operating Procedure |
| SSP | Study-specific procedure |
| SUSAR | Suspected unexpected serious adverse reaction |
| TEAE | Treatment-emergent adverse event |
| TEN | Toxic epidermal necrolysis |
| Th | T-helper cell |
| TLR-9 | Toll-like receptor 9 |
| TMF | Trial Master File |
| ULN | Upper limit of normal range |
| ULOQ | Upper limit of quantification |
| US | United States |
| USP | United States Pharmacopeia |
| V | Visit number (e.g. V1 = first study visit) |
| WBC | White blood cell |
| WHO | World Health Organization |
| WMA | World Medical Association |
| WOCBP | Women of childbearing potential |
| WT | Wild-type |

# 1. PREFACE

This Statistical Analysis Plan (SAP) Part 2 for "A Phase 1/2 Randomized, Placebo-controlled (phase 1) and Active- controlled (phase 2), Observer-blind Trial to Assess the Safety and Immunogenicity of COVIVAC Vaccine Produced by IVAC in Adults 18-59 and ≥ 60 years old in Vietnam" (Protocol: COVIVAC Phase 1/2) describes and expands upon the statistical information presented in the protocol.

This document describes all planned analyses which will be performed for Phase 2 data of the study and provides reasons and justifications for these analyses. It also includes sample tables, figures, and listings planned for the final analyses (see Appendix 1, Appendix 2, and Appendix 3). Regarding the final analyses and Clinical Study Report (CSR), this SAP follows the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines, as indicated in Topic E3 (Structure and Content of Clinical Study Reports), and more generally is consistent with Topic E8 (General Considerations for Clinical Trials) and Topic E9 (Statistical Principles for Clinical Trials). The structure and content of the SAP provide sufficient detail to meet the requirements identified by the US Food and Drug Administration (FDA) and ICH.

This document contains a review of the study design, general statistical considerations, comprehensive statistical analysis methods for efficacy and safety outcomes, and a list of proposed tables and figures. Any deviation from this SAP will be described and justified in protocol amendments and/or in the Clinical Study Report (CSR), as appropriate. The reader of this SAP is encouraged to also review the study protocol for details on conduct of the study and the operational aspects of clinical assessments.

# 2. INTRODUCTION

On 7 January 2020, a novel coronavirus was identified as the cause of a cluster of pneumonia cases first detected in December 2019 in Wuhan, the capital of China's Hubei province,[1] marking the third documented zoonotic transmission event of a coronavirus within the last two decades. Two other highly pathogenic coronaviruses,[1] both of the genus *Betacoronavirus*, also crossed the species barrier during this period: severe acute respiratory syndrome virus (SARS-CoV), which emerged in Guangdong province, China in November 2002, and ultimately led to 8,096 reported cases and 774 deaths in 27 countries before the last infection was detected in July 2003; and the Middle East respiratory syndrome coronavirus (MERS-CoV), which was first detected in Saudi Arabia in June 2012 (where it still circulates in camels) and has led to 2494 laboratory-confirmed cases and 858 deaths.[2] Phylogenic analysis from full-genome sequencing of the novel coronavirus (which became publicly available on 12 January 2020 [GenBank accession no. MN908947.2] indicated that it was also a Betacoronavirus, and that it belonged to the same subgenus (subgenus *Sarbecovirus* [subgroup B]) as SARS-CoV, with which it shares 79% nucleotide identity.[3] Given its taxonomic relationship to SARS-CoV, the novel coronavirus was designated severe acute respiratory syndrome virus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses. By 30 January 2020, the international outbreak of SARS-CoV-2 was declared a Public Health Emergency of International Concern by the World Health Organization

(WHO), which on 11 February 2020 named the disease caused by the virus COVID-19 (coronavirus disease 2019). By March 11, 2020, WHO officially declared the outbreak of COVID-19 a global pandemic.

## 2.1. Burden of Disease

As of 06 January 2021, the confirmed global case count of COVID-19 has risen to over 87 million, and deaths directly due to SARS-CoV-2 infection have surpassed 1.85 million.[4] The large majority of deaths have occurred among the elderly in the United States, Brazil, India and Mexico, which may be largely attributable to poorly implemented control measures (such as surveillance, border closure, quarantine and social distancing) in those countries.[5] While there have been significantly fewer cases to date in most low- and middle-income countries (LMICs), there is great concern about the potential impact of easing of containment efforts, particularly in countries where robust and functioning public health infrastructure is lacking.[6] In addition to the potentially devastating direct disease burden of SARS-CoV-2 in LMICs, the disruptions to routine health services and economic systems due to the pandemic may result in an indirect disease burden of equal or even greater magnitude – a burden that would be borne by all demographic groups. One study has estimated that disruptions to health systems and access to food in LMICs as a result of the COVID-19 pandemic would result in a minimum of 253,500 children under 5 child deaths and 12.200 maternal deaths over a 6-month period. In the worse scenario, there would be 1,157,000 additional under-five child deaths and 56,700 maternal deaths over a 6-month period.[7] In Vietnam, as of 06 January 2021 there have been 1,504 confirmed cases and 35 deaths.

## 2.2. Pathogen and Clinical Disease

Like all viruses in the *Coronaviridae* family, SARS-CoV-2 is an enveloped, positive-sense, single-stranded RNA virus, with a genome that (in addition to a replicase and accessory proteins) encodes four major structural proteins: the spike surface glycoprotein (S), small envelope protein, matrix protein, and nucleocapsid (N) protein. The diagnosis of COVID-19 is made by detection of SARS-CoV-2 RNA by reverse transcription polymerase chain reaction (RT-PCR), with a common gene target being one of the structural proteins. The coronavirus S protein plays the essential role of mediating cell entry by binding to the host-cell receptor, and thus is the primary determinant of viral tropism.[8] The S proteins of SARS-CoV and SARS-CoV-2 bind to the same primary host receptor, the angiotensin-converting enzyme 2 (ACE2) receptor, whereas MERS-CoV (which belongs to a different coronavirus lineage) uses dipeptidyl peptidase 4.

As is the case for both SARS-CoV and MERS-CoV, the median incubation period of SARS-CoV-2 is approximately four to five days after exposure.[9] Similar to SARS-CoV, pneumonia is the most frequent serious manifestation of SARS-CoV-2 infection, with dry cough, fever, myalgia, headache, dyspnea and sore throat being the most common presenting clinical features.[10] Diarrhea, nausea/vomiting, abdominal pain,[11] smell and taste disorders (i.e., anosmia and dysgeusia),[12] and rhinorrhea are also associated with COVID-19, though less commonly. While the spectrum of symptomatic SARS-CoV-2 infection ranges from mild to critical, most cases of COVID-19 are mild (approximately 80%).[13] In addition, multiple

studies now suggest that asymptomatic infection may be very common – as high as 88% by one report.[14] This is in contrast to SARS-CoV, which uncommonly caused mild or asymptomatic disease.[15]

In patients with severe to critical disease (approximately 15% and 5% of total cases, respectively),[13] dyspnea, hypoxia, cytokine release syndrome, acute respiratory distress syndrome, shock, thromboembolic complications, sudden cardiac death and multiorgan failure have been reported.[16] Most patients who die from COVID-19 are older persons (~80% of deaths occur in those > 65 years old)[17] and/or persons with underlying medical comorbidities (obesity, cardiovascular disease, diabetes, chronic lung disease, cancer, chronic kidney disease, hypertension),[18] although severe illness can occur in otherwise healthy persons of any age. In rare cases children can be severely affected, manifesting clinically as a hyperinflammatory syndrome similar to Kawasaki disease (a rare acute pediatric vasculitis)[19] or toxic shock syndrome;[20] this syndrome has been termed multisystem inflammatory syndrome.[21] In multiple cohort studies, male gender is strongly associated with death from COVID-19.[22],[23]

## 2.3. Transmission and Infectivity

Like SARS-CoV, there is considerable evidence that SARS-CoV-2 originated in bats, and was transmitted to humans after amplification in an intermediate host such as the pangolin.[24] Human-to-human transmission is thought to occur as a result of direct contact of virus with the mucous membranes of the infected person, primarily via infected respiratory droplets and aerosols. The risk of transmission from an individual with SARS-CoV-2 infection varies by the type and duration of exposure, factors such as the amount of virus in respiratory secretions, and the use of preventive measures. The interval during which an individual with COVID-19 is infectious appears to be highly variable, with duration of viral shedding dependent upon the severity of the illness.[25] However, it is known that SARS-CoV-2 can be transmitted prior to, or in the absence of the development of symptoms, and throughout the course of illness, with highest levels of virus in the upper respiratory tract – and thus perhaps highest infectivity – soon after symptom onset.[26] It is not known to what extent asymptomatic infection has contributed to the pandemic spread of the virus.[27]

## 2.4. Vaccine Development

Based on a basic reproduction number ($R_0$) of ~2-3,[28] 60% to 70% of the population would need to develop immunity to SARS-CoV-2 for pandemic spread to be contained in the absence of significant control measures. Recent seroprevalence surveys indicate that population immunity remains well below this threshold in countries with the highest burden of COVID-19.[29] These results make clear that herd immunity cannot be achieved through natural infection without incurring very significant additional costs to society in terms of mortality, morbidity, and ongoing economic and social disruption, and that the only acceptable route to achieving herd immunity is widespread – and ideally rapid – deployment of an effective vaccine.

Studies conducted previously in support of SARS-CoV and MERS-CoV vaccine development were instrumental in accelerating development of SARS-CoV-2 candidates. The fact that many COVID-19 vaccine programs have moved quickly with selection of the S protein as target antigen was due to prior preclinical and human immunology studies on SARS-CoV demonstrating that the S protein of SARS-CoV elicits neutralizing antibodies that are protective against SARS-CoV challenge (by blocking virus attachment and fusion, as well as possibly by triggering FcR-mediated cytolysis or phagocytosis), and that these antibodies persist in convalescent serum of patients who have recovered from SARS.[30] Not long after the onset of the COVID-19 pandemic it was similarly demonstrated that the S protein of SARS-CoV-2 induces anti-S IgG antibodies in infected humans that neutralize the virus in animal models,[31] and that these antibodies persist for many months in convalescent sera.[32] While it is likely that induction of CD8+ T-cells against S as well as other viral proteins [33] plays a complementary role in protection after natural infection, the importance of a robust anti-S IgG neutralizing antibody response in protection against disease after natural infection[34] or experimental vaccination[35] is now incontrovertible.

A large number of vaccine candidates employing a large diversity of vaccine platforms (mRNA, DNA, subunit, viral vectors, nanoparticle) are in development, many candidates that are currently in late stage Phase 3 development.[36] Two of these vaccines, Pfizer/BioNTech's and Moderna's mRNA-based vaccines that encode the full-length S protein with two stabilizing proline mutations (S-2P) have been shown to have an efficacy against COVID-19 of greater than 90% after a two-dose regimen. These results, along with supportive early-phase study results from multiple other S-protein-based candidate vaccines that have elicited high-titer neutralizing antibodies further validate the selection of the S protein as target antigen.[37]

## 2.5. Risk of Immune Enhancement

In addition to facilitating target antigen selection, preclinical studies of SARS-CoV and MERS-CoV vaccines have also highlighted the potential risk of a SARS-CoV-2 vaccine exacerbating disease caused by subsequent SARS-CoV-2 infection. An inactivated SARS-CoV vaccine was shown to induce disease enhancement in rhesus monkeys subsequently challenged with SARS-CoV, as a result of non-neutralizing antibodies generated by the vaccine against the SARS-CoV S protein.[38] Such antibody-dependent enhancement (ADE) also occurred in cats infected with the Alphacoronavirus feline infectious peritonitis virus (FIPV), after being vaccinated with an inactivated FIPV vaccine.[39] Vaccine-induced non-functional antibodies cause ADE by facilitating viral entry into host cells, by increasing binding efficiency of virus-antibody complexes to host cells via Fc receptors on those cells.[40]

A second mechanism by which immune enhancement of disease may occur is via vaccine-induced inflammation.[41] Apart from activating Fc-receptor mediated endocytosis, vaccine-induced antibodies may elicit Fc-mediated responses, such as complement activation and antibody-dependent cellular cytotoxicity (ADCC), that may contribute to immunopathology. This phenomenon was observed in ferrets and Cynomolgus monkeys challenged with SARS-CoV following vaccination with an inactivated whole SARS-CoV vaccine; [42] the animals developed lung immunopathology characterized by eosinophilic recruitment, increased

mucus production and airway hyperresponsiveness. The same immunopathology was observed in 1966 in children given formalin-inactivated respiratory syncytial virus (RSV) vaccine who subsequently were infected by RSV. [43] Enhancement of RSV disease in that study led to frequent hospitalizations and, in the youngest cohort, two deaths.[44] The prominence of eosinophils with such lung immunopathology has often been interpreted as signifying that this immune enhancement was the result of Th2-biased immune responses.

To date, there has been no evidence of antibody-dependent disease enhancement or immunopathology in animal studies and human trials of SARS-CoV-2 candidate vaccines. This is likely due to the fact that these candidates, including an inactivated SARS-CoV-2 vaccine,[45] have been shown to elicit high-titer anti-S neutralizing antibody responses. SARS-CoV-1 vaccines that elicit neutralizing antibodies against the SARS-CoV S protein were similarly able to protect animals from SARS-CoV challenge without evidence of acute lung injury and immunopathology.[46] In addition, many SARS-CoV-2 vaccine candidates include Th1-polarizing adjuvants to minimize the risk of disease enhancement. Nevertheless, disease enhancement remains a theoretical risk, particularly after waning of antibody responses, and therefore needs to be closely monitored in human clinical trials of SARS-CoV-2 vaccines.

## 2.6. Introduction to COVIVAC Vaccine

Given the global scope of the COVID-19 pandemic, there is an urgent need for a safe and effective vaccine against COVID-19 that will be affordable and able to be manufactured at a sufficient scale to supply Vietnam and other low- and-middle-income countries. To achieve this aim, IVAC and two other consortium manufacturers – the Government Pharmaceutical Organization (GPO), Thailand and Instituto Butantan, Brazil – are independently developing an inactivated whole chimeric virion vaccine based on a Newcastle Disease Virus (NDV) that has been modified to also express the SARS-CoV-2 S protein on its surface. This technology was invented at the Icahn School of Medicine at Mount Sinai (ISMMS) (New York, New York, USA). Since NDV grows well in embryonated chicken eggs, the NDV chimeric vaccine can be manufactured using the same inexpensive egg-based process employed for inactivated influenza virus vaccine (IIV).[47] In addition to taking advantage of the cost-effectiveness of the manufacturing process, an inactivated chimeric NDV vaccine propagated in eggs (prior to being inactivated by beta-propiolactone [BPL]) is also expected to be as safe as egg-based IIV, which has an excellent safety profile, including in infants, pregnant women, and elderly adults.

As in the case of many COVID-19 vaccines currently in development, the inactivated chimeric NDV vaccine expresses the ectodomain of the SARS-CoV-2 S protein – which is fused to the F protein transmembrane domain of NDV, resulting in abundant expression of membrane-bound S antigen. While many candidate COVID-19 vaccines are targeting the S protein as antigen, the S protein expressed on the surface of the chimeric NDV virion is a much more stable construct than that utilized in other COVID-19 vaccines as it contains six stabilizing proline substitutions – four more than are introduced in the S protein antigen (S-2P) used in a number of COVID-19 candidate vaccines, including the Pfizer/BioNTech and Moderna vaccines. The resulting protein, called “HexaPro” (HXP) and developed by the University of Texas (Austin, TX, USA),[48] is more immunogenic (>10-fold higher) than S-

2P in mice (data unpublished), and also provides higher yields than S-2P when expressed recombinantly. As a result of these properties it is expected that significant dose-sparing will be possible with the COVIVAC vaccine candidate relative to other vaccine candidates expressing the earlier-developed S-2P antigen. Dose-sparing translates to higher production volumes and lower cost of vaccine. Finally it is important to note that HexaPro has also been shown to be more thermostable than S-2P.[48] The fact that COVIVAC is expected to be thermally stable at 2-8 °C is a major advantage of the vaccine over other COVID-19 candidates in development that will require storage at -20°C or even lower temperature.

While it is likely that the whole virion COVIVAC vaccine alone will prove to be highly immunogenic in healthy adults due to endogenous adjuvanticity of the NDV virion, use of exogenous adjuvant may further increase the functional immune response to the vaccine – which may be important to ensure adequate protection in older adults, or possibly provide additional opportunity for dose-sparing. For this reason, the first part of this combined Phase 1/2 study is a first-in-human, Phase 1 evaluation of a 2-dose regimen of both unadjuvanted COVIVAC (at 1 µg, 3 µg, and 10 µg dose levels) and COVIVAC adjuvanted with CpG 1018 (at the 1 µg dose level) in healthy adults. CpG 1018, the adjuvant in the US-licensed HEPLISAV-B® vaccine (Dynavax Technologies Corporation, Emeryville, CA, USA), is a synthetic 22-mer oligodeoxynucleotide that exerts its action by targeting toll-like receptor 9 (TLR-9) expressed on a few key immune-cell types. When used as a vaccine adjuvant, CpG 1018 increases antibody concentrations to co-administered antigen, stimulates helper (CD4+) and cytotoxic (CD8+) T cell populations and generates robust T and B cell memory responses. Additionally, CpG 1018 strongly favors development of the Th1 subset of helper T cells, the type of helper T cell that is essential for protection from infections with viruses and intracellular bacteria. HEPLISAV-B was well-tolerated and shown to have an adequate safety profile in clinical trials in adults.[49] Interim analyses of an ongoing post-marketing study of over 30,000 HEPLISAV-B recipients and more than 35,000 active comparator recipients have raised no safety concerns.

## 2.7. Purpose of the Analyses

The main purpose of this study is to evaluate the safety, tolerability and immunogenicity of COVIVAC vaccine across a range of S-antigen dose levels – one with CpG 1018 as adjuvant – with the aim of expeditiously selecting a single candidate to advance to Phase 3 studies. The proposed dosing regimen for the tested vaccines is to administer two doses with 28-day interval. The period of 28 days between prime and boost was selected because it is the acceptable dosing interval for many licensed vaccines and other COVID-19 vaccines which are being developed. The analysis of data from Phase 1 will provide justification for advancement to the Phase 2 segment based on safety evaluations during an initial sentinel dose-escalation stage, and later an interim analysis of safety and immunogenicity (the latter primarily based on pseudovirus neutralization) through 28 and 14 days after the first and second dose, respectively.

An independent Data and Safety Monitoring Board (DSMB) will review unblinded safety data through Day 57, and on the basis of this review provide a recommendation for advancing

to Phase 2 (the DSMB will also be convened at any time during conduct of the study in the event that a study pause rule is triggered).

If warranted, the two optimal COVIVAC formulations will be selected for ongoing evaluation in Part 2 of the study based on the safety and immunogenicity results of the Phase 1 interim analysis. The Phase 2 segment of the study will include a sufficient number of older adults aged ≥60 (including those with stable chronic co-morbidities) to determine whether safety and immunogenicity of the vaccine may differ in this older population. It is critical that evaluation of COVIVAC in older adults informs the selection of the COVIVAC candidate to advance to Phase 3 studies (based on safety and immunogenicity through 14 days post-second vaccination in Phase 2), given the higher risk of severe COVID-19 in this age group, and the potential need for a higher dose level of antigen and/or use of adjuvant to achieve a comparable functional immune response as younger adults. Phase 2 immunogenicity and safety data through Day 43 and Day 57, respectively, will determine the vaccine composition to advance to Phase 3, registration, and commercialization. Cell-mediated immunity will also be evaluated in a subset of subjects in the Phase 2 segment as an exploratory objective to assess the S protein-specific T cell response including Th polarization.

In addition to standard safety monitoring throughout the study, subjects will be evaluated for specific adverse event of special interest (AESI); these include potential immune-mediated medical conditions, which may be associated with vaccination. In addition subjects will be closely monitored for adverse events associated with COVID-19 to identify, and treat if indicated, potential cases of COVID-19 during the trial, and to assess for possible vaccine-induced immune enhancement of disease. In addition to mandatory use of masks and other exposure control measures by staff and subjects during clinic visits, study subjects will be instructed to contact the Principal Investigator (PI) if they meet criteria for COVID-19 testing based on specified signs and symptoms; these criteria will be provided to subjects in the form of a fact sheet.

To maintain the study blinded so that there is no bias in the ascertainment and interpretation of the safety and immunogenicity data, a control group is included. While in the Phase 1 a placebo group was chosen as the control, it is perceived that for the Phase 2 it will be practically difficult, and potentially ethically unacceptable to enroll subjects to receive placebo. Therefore, the Phase 2 part of the study has been redesigned to include an active comparator group (a vaccine in use by public health systems in Vietnam (e.g., AstraZeneca's). This change also allows for the possibility of comparing the immunogenicity of the selected doses to an emergency approved widely used around the world. In order to optimize comparison the number of subjects in the control arm (comparator) has been increased to 125 subjects, to be randomized with the two COVIVAC arms.

The ultimate aim of developing COVIVAC vaccine for the prevention of COVID-19 is to obtain local registration of the vaccine in Vietnam, followed by prequalification by the WHO, with the goal of providing affordable access to a life-saving COVID-19 vaccine for Vietnam and other LMICs.

This SAP Part 2 describes the statistical methodology and summaries required to assess the

safety tolerability and immunogenicity of COVIVAC vaccine across the two COVIVAC vaccines to select a single candidate to advance to Phase 3.

# 3. STUDY OBJECTIVES AND ENDPOINTS – PHASE 2

The Phase 2 study objectives are listed here as in the protocol.

## 3.1. Study Hypotheses

**Safety, Tolerability:**

- The COVIVAC vaccine (NDV-HXP-S) will have an acceptable safety profile and be well-tolerated when administered as a two-dose regimen at 3 ug and 6 ug doses, both without CpG, in the phase 2 study. Safety and tolerability of the vaccine will be comparable to those of AstraZeneca vaccine, which will be used as an active comparator in the phase 2 study.

**Immunogenicity:**

- COVIVAC will elicit a measurable and dose-dependent neutralizing antibody response, comparable to that of the AstraZeneca

## 3.2. Primary Objective

**PHASE 2**

**Safety, Tolerability**

**Primary Objectives**

1. To assess the safety and tolerability of two dose levels of COVIVAC (3 µg and 6 µg, without CpG) and AZD1222 vaccine administered at the standard approved dose at a 28-days interval. Safety and tolerability will be compared between the two COVIVAC dose levels
   Note: safety assessments will be stratified into two age groups: 18-59 and ≥60 years

**Primary Endpoints**

1. Number and severity of solicited local and systemic adverse events (AEs) during the first 7 days after each vaccination
2. Number, severity and relatedness of all unsolicited AEs during the first 28 days after each vaccination
3. Number, severity and relatedness of serious adverse events (SAEs) throughout the 7-month study period
4. Number, severity and relatedness of medically-attended AEs (MAAEs) throughout the 7-month study period
5. Number, severity and relatedness of adverse events of special interest (AESI) throughout the 7-month study period, including AESI relevant to COVID-19, and potential immune-mediated medical conditions (PIMMC)

**Secondary Objectives**

1. To compare the safety and tolerability of each of the two dose levels of COVIVAC vaccine with those of AZD1222

**Secondary Endpoints**

1. Comparison of the same parameters listed for primary endpoints above

**Immunogenicity**

**Primary Objectives**

1. To assess the functional (neutralization) humoral immune response elicited by each of two selected COVIVAC formulations, as measured by 50% neutralization ($NT_{50}$) pseudovirus neutralization assay (PNA) at baseline and 14 days and 6 months after the second vaccination, in adults ≥18 years old
2. To assess the functional (neutralizing) humoral immune response elicited by each of two selected COVIVAC formulations, as measured by PNA at baseline and 14 days and 6 months after the second vaccination, separately in adults aged 18-59 and ≥ 60 years

**Primary Endpoints:**

1. 50% neutralizing antibody ($NT_{50}$) geometric mean titer (GMT) against SARS-CoV-2 pseudovirus at baseline and 14 days and 6 months after the second vaccination in all the subjects *(note: the primary analysis will be conducted separately for those who are anti-S IgG seronegative at baseline (no pre-screening for SARS-CoV-2 will be carried out)*
2. Geometric mean fold rise (GMFR) (from baseline) in NT50 against SARS-CoV-2 pseudovirus at 14 days and 6 months after the second vaccination
3. Percentage of subjects with $NT_{50}$ seroresponses against SARS-CoV-2 pseudovirus as defined by a ≥ 4-fold increase from baseline to 14 days after the second vaccination

Notes: 1) the primary analysis will be conducted separately for those who are anti-S IgG seronegative at baseline (as an outbreak control measure the Vietnam Ministry of Health requires that all potential participants attending the visit of inform consent process and screening be tested for SARS-CoV-2 by RT-PCR. This is a non-study procedure conducted by non-study staff of Thai Binh CDC)2) comparisons of the parameters above will be made between each of the COVIVAC arms and the AZD1222 arm; 3) comparisons of the parameters above will be made between each of the COVIVAC arms and the AZD122 arm

**Secondary Objectives**

1. To assess the IgG immune response elicited by each of two selected COVIVAC formulations and the AZD1222 comparator against the S protein of SARS-CoV-2, as measured by ELISA, at baseline and 14 days and 6 months after the second vaccination
2. To assess the IgG immune response elicited by each of two selected COVIVAC formulations and the AZD1222 comparator against the S protein of SARS-CoV-2, as measured by ELISA, at baseline and 14 days and 6 months after the second vaccination, separately, in adults 18-59 and ≥ 60 years of age
3. To compare the neutralization immune responses observed at each dose level of COVIVAC with the corresponding responses observed with the AstraZeneca active comparator vaccine.

**Secondary Endpoints:**

1. Anti-S IgG GMT at baseline and at 14 days and 6 months after the second vaccination

2. GMFR (from baseline) in anti-S IgG GMT at 14 days and 6 months after the second vaccination
3. Percentage of subjects with seroresponses in anti-S IgG titer as defined by a ≥ 4-fold increase from baseline to 14 days and 6 months after second vaccination
4. 50% neutralizing antibody ($NT_{50}$) geometric mean titer (GMT) against SARS-CoV-2 pseudovirus at baseline and 14 days and 6 months after the second vaccination in all the subjects

**Exploratory Objectives**

**Immunogenicity:**

1. To assess the S protein-specific T cell response elicited by each of two selected COVIVAC formulations and the AZD1222 comparator as measured by enzyme-linked immunospot assay (ELISpot), at baseline and 14 days and 6 months after the second vaccination, in a subset of subjects
2. To assess the S protein-specific T cell responses as measured by ELISpot at baseline and 14 days and 6 months in each of the study arms after the second vaccination in subsets of adults aged 18-59 and ≥ 60 years old
3. To assess the neutralization of COVID-19 variants of concern (VOC) in subsets of subjects from each of the study arms

**Exploratory Endpoints:**

1. Magnitude, functionality and T helper cell (Th) polarization of S-protein specific T cells relative to baseline at 14 days and 6 months after the second vaccination
2. 50% neutralizing antibody ($NT_{50}$) geometric mean titer (GMT) against SARS-CoV-2 variants of concern at baseline, 14 days and 6 months after the second vaccination in subsets of subjects

## 3.3. Study Definitions and Derived Variables

### 3.3.1. Adverse Event

An adverse event is any untoward, undesired, or unplanned event in the form of signs, symptoms, disease, or laboratory or psychological/physiologic observations occurring in a subject enrolled in the clinical trial. This includes all subjects from whom consent has been obtained whether or not they have yet been randomized and received a study product. The event does not need to be causally related to trial participation or receipt of a study product. An AE is temporally related to participation in the study and will be documented as to whether or not it is considered to be related to vaccine. An AE includes, but is not limited to, the following:

- An intercurrent illness or injury during the course of the study
- Any clinically significant worsening of a preexisting condition

### 3.3.2. Solicited Adverse Event

Solicited adverse events are pre-specified injection-site-specific local and systemic AEs that occur relatively more frequently, or are known to be associated with, immunization, and which

are monitored actively as potential indicators of vaccine reactogenicity. Investigators will not be required to assess causality of solicited AEs if the onset is during the solicitation period.

The following specific solicited AEs will be monitored for this study:

Local solicited AEs assessed at the injection site:

- Pain or tenderness
- Swelling or induration
- Erythema

Systemic solicited AEs:

- Fever (defined as oral temperature ≥ 38°C)
- Headache
- Fatigue or malaise
- Myalgia
- Arthralgia
- Nausea or vomiting

### 3.3.3. Unsolicited Adverse Event

An unsolicited adverse event is any AE reported spontaneously by the subject, observed by the study staff during study visits or those identified during review of medical records or source documents. Solicited AEs with an onset after the seven-day solicitation period will be considered unsolicited AEs. In the absence of a diagnosis, abnormal physical examination findings or abnormal clinical safety laboratory test results that are assessed by the investigator to be clinically significant will be recorded as an AE.

### 3.3.4. Medically-Attended Adverse Event

A medically-attended adverse event is an unsolicited AE for which the subject received medical attention, such as during an emergency room visit or a visit to or from medical personnel (e.g., medical doctor).

### 3.3.5. Adverse Event of Special Interest

An adverse event of special interest (AESI) is an AE of scientific and medical concern specific to the Sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the Sponsor can be appropriate. Such an event might warrant further investigation in order to characterize and understand it.

The AESI to be monitored in this study include the following:

- Potential immune-mediated medical conditions (PIMMC), given that vaccination has been associated with autoimmunity

- AEs associated with COVID-19, given the importance to subject safety of managing any occurrence of COVID-19, and the possible association of vaccination with enhancement of COVID-19

### 3.3.6. Protocol-Related Adverse Event

A protocol-related adverse event is an AE that occurs from the time of enrollment until the EOS visit that is not considered to be related to receipt of the study vaccine, but is considered by the PI/designee or the Sponsor to be related to the research conditions, i.e., related to the fact that a subject is participating in the study. For example, a protocol-related AE may be an untoward event occurring during blood sampling or other protocol-specified activity.

### 3.3.7. Treatment-Emergent Adverse Event

A treatment-emergent AE is defined as an AE that is not present prior to administration of the study product, or, if present prior to the administration of the study medication, increases in intensity after administration of the study medication during the course of the study.

### 3.3.8. Serious Adverse Event

An SAE is a specific AE that:

- Results in death.
- Is life-threatening.*
- Requires inpatient hospitalization or prolongation of an existing hospitalization.**
- Results in a persistent or significant disability or incapacity.***
- Results in a congenital anomaly or birth defect.

***Life-threatening** refers to immediate risk of death as the event occurred per the reporter. A life-threatening event does not include an event that, had it occurred in a more severe form, might have caused death but, as it actually occurred, did not create an immediate risk of death.

For example, hepatitis that resolved without evidence of hepatic failure would not be considered life-threatening, even though hepatitis of a more severe nature can be fatal. Similarly, an allergic reaction resulting in angioedema of the face would not be life-threatening, even though angioedema of the larynx, allergic bronchospasm, or anaphylaxis can be fatal.

****Hospitalization** is an admission to a health facility in the situation where there is an AE. A period of observation at a clinical trial site is not considered to represent hospitalization for the purposes of SAE reporting. Hospitalization or prolongation of a hospitalization constitutes a criterion for an AE to be serious; however, it is not in itself considered an SAE. In absence of an AE, a hospitalization or prolongation of a hospitalization should not be reported as an SAE by the PI/designee on a SAE form. Such situations include, but are not limited to, the following:

- A hospitalization for a preexisting condition that has not worsened.
- Hospitalization for social reasons.

***Disability** is defined as a substantial disruption in a person's ability to conduct normal life functions. If there is any doubt about whether the information constitutes an SAE, the information is treated as an SAE.

Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as **important medical events** that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, or blood dyscrasias or convulsions that do not result in hospitalization.

### 3.3.9. Severity (Intensity) of Adverse Event

The severity of all solicited AEs will be graded from Mild (Grade 1) to Potentially Life Threatening (Grade 4). All AEs leading to death are Grade 5 events. Adverse events are graded based on the worst severity grade during the illness/symptoms. All other unsolicited AEs will be classified as an AE and graded based on the AE severity scale in table of severity grading below. The grading scales for solicited and unsolicited AEs have been derived from the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (Version 2.1, July 2017), from the US National Institutes of Health.

**Table of Severity Grading – Protocol Table 6**

| Grade | Description |
|---|---|
| 1 | Causes no or minimal interference with normal daily activities; intervention not indicated |
| 2 | Interferes with but does not prevent normal daily activities; intervention indicated |
| 3 | Prevents normal daily activities; intervention or hospitalization indicated |
| 4 | Causes inability to perform basic self-care activities; intervention indicated to prevent permanent impairment, persistent disability, or death |

### 3.3.10. Causal Relationship of an Adverse Event

A suspected adverse drug reaction (ADR) means any AE for which there is a reasonable possibility that the study vaccine caused the AE. A reasonable possibility means there is evidence to suggest a causal relationship between the vaccine and the AE. All cases judged by either the PI/designee or the Sponsor as having a reasonable suspected causal relationship to the study vaccine will qualify as ADRs. Medical judgment will be used to determine the relationship, considering all relevant factors, including pattern of reaction, temporal relationship, confounding factors such as concomitant medication, concomitant diseases, and relevant history.

The likelihood of the relationship of the AE to study vaccine is to be recorded as follows:

- Related: There is a reasonable causal relationship between the vaccine administered and the AE.

- Not Related: There is no reasonable causal relationship between the vaccine administered and the AE.

Note: Solicited reactogenicity events will not be judged for relatedness.

### 3.3.11. Assessment of Outcome of Adverse Event

The outcome of the AE will be assessed and recorded as per the following categories:

- Ongoing
- Recovered/resolved
- Recovered/resolved with sequelae
- Fatal
- Unknown

### 3.3.12. Adverse Event Recording and Reporting

Recording and reporting of all AEs will occur from signing of the ICF (enrollment) through 28 days post-second injection (Visit 6) for each study subject receiving study product. SAEs, MAAEs, and AESI will be recorded throughout the study period. The Study staff must completely and promptly record each AE in the source documentation and on the AE CRF, regardless of relationship to the vaccine administered/procedure as determined by the PI/designee. The PI/designee will attempt, if possible, to establish a diagnosis based on the signs and symptoms. When a diagnosis for the reported signs or symptoms is known, the PI/designee will report the diagnosis as the AE, not the signs and symptoms. Adverse events will be classified by MedDRA term and by severity/intensity, relatedness, and outcome.

Enrolled subjects who subsequently screen fail (i.e., who never underwent randomization) will have any AEs recorded from enrollment until the time they are determined to be ineligible for randomization or withdraw consent. These AEs will be listed in separate appendices from those subjects randomized and vaccinated. For the purposes of data capture they will be closed at the point the subject is deemed ineligible.

Reporting of AEs will follow the regulatory guidelines of the Ministry of Health and NIHE's Ethics Committee (EC) in regard to requirements, processes and forms.

### 3.3.13. Serious Adverse Event Reporting

If an AE is classified as serious, an SAE form will be completed and submitted within 24 hours of the PI/designee becoming aware of the SAE, including information on the location, severity, relatedness, and clinical summary of the event to the Sponsor to initiate any PSRT evaluation and any additional reporting requirements. In addition, the SAE submission will follow the regulatory guidelines of the Ministry of Health and NIHE's IRB in regards to requirements, processes and forms. It is the responsibility of the Sponsor to ensure that Dynavax Technologies Corporation (manufacturer of the adjuvant CpG 1018) and the other Consortium manufacturers are notified of SAEs and other notable safety events per agreed procedures and timelines. Any SAE deemed related to study vaccine that is ongoing at the time of last subject

last visit (LSLV) will continue to be followed until it is resolved, assessed to be resolved with sequelae, or assessed to be stable/chronic. SAEs deemed not related to study vaccine that are unresolved at the time of LSLV will be classified as ongoing.

### 3.3.14. Unanticipated Problems

All unanticipated problems will be reported in the continuing review report submitted to the Ministry of Health and NIHE's IRB per reporting requirements of each regulatory body. All serious unanticipated problems involving risk to participants or others will be promptly (within 48 hours) reported by telephone, by email, or by facsimile to the Sponsor. Follow-up reports will be submitted as soon as additional information becomes available.

# 4. INVESTIGATIONAL PLAN

## 4.1. Overall Study Design and Plan

This prospective, single-center, randomized, placebo-controlled (Phase 1) and active-controlled (Phase 2), observer-blind Phase 1/2 study includes two separate parts. The treatment groups to be evaluated in each part of the study (and their corresponding sample size) are presented in Table 1.

**Table 1: Treatment Groups - Protocol Table 3**

| Phase | Group | Sample Size | Study Product |
|---|---|---|---|
| 1 | 1 | 20 | Placebo |
| | 2 | 25 | COVIVAC 1 µg |
| | 3 | 25 | COVIVAC 3 µg |
| | 4 | 25 | COVIVAC 10 µg |
| | 5 | 25 | COVIVAC 1 µg + CpG1018 |
| 2 | 1 | 125 | AstraZeneca |
| | 2 | 125 | COVIVAC 3 µg |
| | 3 | 125 | COVIVAC 6 µg |

In Part 2 of this combined Phase 1/2 study, 375 adults aged 18 to ≥ 60 years of aged will be randomized (1:1:1) to comparator vaccine, or one of two selected doses of COVIVAC, 3 µg (being evaluated in Phase 1) and 6 µg (an intermediate dose level not tested in the Phase 1, but lower than the maximum tested on the Phase 1 trial). The Phase 2 cohort will follow the same visit schedule, and undergo the same procedures and assessments, as in Phase 1 (except that the V4/D36 visit is conducted by phone/home visit instead of site visit and no blood will be collected for immunogenicity testing on Day 28 (i.e., 4 weeks after the first dose).

An interim analysis of Phase 2 data will be conducted after the last subject of the Phase 2 cohort completes V6 (D57) as the basis for selecting the optimal formulation of COVIVAC to advance to Phase 3 studies. As was the case for the Phase 1 interim analysis at the same timepoint, the data generated will include unblinded post-dose 1 and dose 2 safety results for review by the DSMB which includes safety results at the aggregate treatment level (in the case of rare events occurring in only one treatment group, these will be added with an asterisk in all groups for Sponsor review) and immunogenicity results aggregated by treatment group. The DSMB will consider all accumulated safety data from both phases of the study prior to making any recommendation to the Sponsor that it not advance a formulation based on safety concerns. The Sponsor will ultimately select the formulation to advance to Phase 3 based on the DSMB assessment of safety and tolerability profile, the relative functional immunogenicity and other programmatic considerations such as those noted above.

**Table 2: Visit Schedule - Phase1 and Phase 2**

| | | V1 | V2 | V3 | V4[$] | V5 | V6 | V7 |
|---|---|---|---|---|---|---|---|---|
| **Day (+ window)** | **-42 to 1** | **1** | **8 (+3)** | **29 (+3)** | **36 (+3)** | **43 (+3)** | **57 (+7)** | **197 (+14)** |
| **Screening** | **X** | | | | | | | |
| **Vaccination** | | **1** | | **2** | | | | |
| **Immune labs Pseudovirus NT IgG ELISA*** | | **X** | | **X[$]** | | **X** | | **X** |
| **CMI[#]** | | **X** | | **X** | | **X** | | **X** |
| **Safety data collection:** | | | | | | | | |
| **Safety visits** | **X** | **X** | **X** | **X** | **X[$]** | **X** | **X** | **X** |
| **Clinical labs[@]** | **X[@]** | | **X[$]** | | **X[$]** | | | |
| **Reactogenicity** | | → | → | → | → | | | |
| **AEs** | → | → | → | → | → | → | → | |
| **MAAEs** | → | → | → | → | → | → | → | → |
| **AESI** | → | → | → | → | → | → | → | → |
| **SAEs** | → | → | → | → | → | → | → | → |

[*] Anti-NDV ELISA in Phase 1 only, at V1, V5, and V7

[#] Phase 2 only, in subset of subjects

[$] Phase 1 only. In Phase 2, study staff will make a phone call/home visit to remind subject to complete the diary card; the diary card for dose 2 will be collected and reviewed on the V5/D43 visit (2 weeks after vaccination)

[@] **Phase 1 only**

***Note:*** *The study dates of visits after the V3/D29 visit will be adjusted according to the actual date of the V3/D29 visit.*

## 4.2. Selection of Study Population

### 4.2.1. Description of Study Population

The study population will consist of eligible, Vietnamese male and female adults 18-59 and ≥ 60 years old, inclusive.

### 4.2.2. Inclusion Criteria for Enrollment

**Phase 2:**

1. Adult ≥ 18 years and ≥ 60 years of age inclusive at the time of randomization.
2. Having no clinically significant acute medical condition, and no chronic medical condition that has not been controlled within 90 days of randomization, as determined by medical history, physical examination, screening laboratory test results, and clinical assessment of the investigator.
3. Has provided written informed consent prior to performance of any study-specific procedure.
4. Has a body mass index (BMI) of 17 to 40 kg/m$^2$, inclusive, at screening.
5. Resides in study site area and is able and willing to adhere to all protocol visits and procedures.
6. If a woman is of childbearing potential age, must not be breastfeeding or be pregnant (based on a negative urine pregnancy test at screening and during the 24 hours prior

to receipt of the first dose of IP), must plan to avoid pregnancy for at least 28 days after the last dose of IP, and be willing to use an adequate method of contraception consistently and have a repeated pregnancy test prior to the second (last) dose of IP.

### 4.2.3. Exclusion Criteria for Enrollment

Participants will be ineligible for this study for any of the following conditions or reasons:

1. Use of any investigational medicinal product within 90 days prior to randomization or planned use of such a product during the period of study participation.
2. History of administration of any non-study vaccine within 28 days prior to administration of study vaccine or planned within 3 months after enrolment.
   **Note:** receipt of any COVID-19 vaccine that is licensed or granted Emergency Use Authorization in Vietnam during the course of study participation is not exclusionary if administered after Visit 5.
3. Previous receipt of investigational vaccine for SARS or MERS, or any investigational or licensed vaccine that may have an impact on interpretation of the trial results.
4. History of hypersensitivity reaction to any prior vaccination or known hypersensitivity to any component of the study vaccine.
5. History of egg or chicken allergy.
6. History of angioedema.
7. History of anaphylaxis (≥ Grade 2).
8. Acute illness (moderate or severe) and/or fever (body temperature measured orally ≥38°C).
9. Any abnormal vital sign deemed clinically relevant by the PI.
10. Abnormality in screening laboratory test deemed exclusionary by the PI in consultation with the Sponsor.
11. A positive serologic test for hepatitis B (HBsAg) or hepatitis C (HCV Ab) (Phase 1 only).
12. History of confirmed HIV.
13. History of laboratory-confirmed COVID-19.
14. History of malignancy, excluding non-melanoma skin and cervical carcinoma in situ.
15. Any confirmed or suspected immunosuppressive or immunodeficient state.
16. Administration of immunoglobulin or any blood product within 90 days prior to first study injection or planned administration during the study period.
17. Administration of any long-acting immune-modifying drugs (e.g., infliximab or rituximab) or the chronic administration (defined as more than 14 days) of immunosuppressants within six months prior to first study injection, or planned administration during the study period (includes systemic corticosteroids at doses equivalent to ≥ 0.5 mg/kg/day of prednisone; the use of topical steroids including inhaled and intranasal steroids is permitted).
18. History of known disturbance of coagulation or blood disorder that could cause anemia or excess bleeding (e.g, thalassemia, coagulation factor deficiencies).
19. Recent history (within the past year) or signs of alcohol or substance abuse.

20. Any medical, psychiatric or behavior condition that in the opinion of the PI may interfere with the study objectives, pose a risk to the subject, or prevent the subject from completing the study follow- up.
21. Employee of any person employed by the Sponsor, the contract research organization (CRO), the PI, study site personnel, or site.

**Note:** specific exclusion criteria (e.g., ≥ Grade 2 acute illness, or abnormal vital sign deemed clinically relevant by the PI/designee) will be reassessed at both vaccination visits. Any subject who cannot be vaccinated due to an acute abnormality assessed at a vaccination visit (Visit 1 or Visit 3) may return once the acute issue has resolved, if deemed appropriate by the PI/designee. A minimum of 48 hours must have passed after a documented fever before a subject can be vaccinated. This safety requirement will not be deemed a protocol deviation should the visit fall outside the vaccination window; however, it will be encouraged to maintain the vaccination window whenever possible in these situations. Clinical laboratory test results and vital signs used to determine subject eligibility will be those obtained at screening. These tests may be repeated once if deemed appropriate by the investigator and determined to be due to a transient condition that has resolved. In addition, a test may also be repeated for test results determined to be spurious by the investigator (e.g., following improper specimen collection). The last measurement will be taken as the baseline for purposes of analysis.

## 4.3. Study Product

### 4.3.1. Product Descriptions

COVIVAC is an inactivated NDV chimera expressing a trimeric pre-fusion form of the SARS-CoV-2 S protein that contains six proline mutations (HexaPro). The vaccine is a clear and slightly opalescent liquid.

All study vaccine products to be administered on a given day (based on the study stage) will be formulated separately by the assigned site staff under aseptic conditions at the start of the clinic day. A detailed mixing procedure will be provided in the Pharmacy Manual or SOP for study product preparation. Each vaccine product will be formulated by filling a 4 ml (4R) [with the height of 46 mm and diameter of 16/1 mm] USP Type I glass vial with bulk drug substance, bulk adjuvant (if indicated based on formulation) and phosphate-buffered saline (PBS) to allow for five 0.5 ml doses per vial, as well as sufficient residual volume for possible dose verification. Each vial label will include the following information: name of the medicinal product, composition, fill volume, route of administration, lot number, manufacturing date, storage condition, and a cautionary statement (“For Clinical Trial Use Only”).

For the Phase 2: study vaccine of 2 selected dose levels is already prepared and filled with the volume of 6 ml in 10 ml vials. Each vial includes 10 doses of 0.5 ml. The remaining volume of vials after being drawn will be returned to the sponsor. Active control is AstraZeneca vaccine which has been granted the EUA and has been used widely in Vietnam.

### 4.3.2. Identity of Investigational Product

**Investigational Vaccine for Phase 2:**

Inactivated Newcastle Disease Virus (NDV) chimera expressing a trimeric pre-fusion form of the SARS-CoV-2 Spike (S) protein that contains six proline mutations (HexaPro, HXP); for intramuscular (IM) administration.

**Control product for Phase 2:**

Authorized Covid-19 vaccine: AstraZeneca AZD1222

## 4.4. Method of Assigning Participants to Treatment Groups (Randomization)

The randomization scheme was generated and maintained by Center of Excellence for Biomedical and Public Health Informatics (BIOPHICS).

After the interim analysis of data from the first phase informs the down selection to two candidate vaccines, 375 adults ≥18 and ≥ 60 years old will be randomized (1:1:1) to AstraZeneca, or one of two selected formulations of COVIVAC 3 µg (evaluated in Phase 1) and 6 µg (an intermediate dose level) based on Phase 1 safety and immunogenicity results. Twelve (12) subjects in each of the three Phase 2 groups (equally distributed between the three age strata) will be selected for CMI at the time of randomization. Randomization will be age stratified by group with approximately one third of subjects in 18-39, 40-59, and ≥60 years of age.

## 4.5. Blinding

A limited number of appropriately trained, unblinded study staff, including the site pharmacist, will be responsible for preparing study products (in accordance with the randomly determined assignment), administering the study vaccine, and handling all drug accountability procedures. These personnel will not participate in the other aspects of the clinical trial, to help ensure the integrity of the blind at the site. The unblinded staff will not reveal subjects' randomization assignments to subjects, or staff associated with the Sponsor, CRO, or site.

Randomization data are kept strictly confidential, and should be accessible only to authorized persons, until the time of unblinding.

### 4.5.1. Unblinding Procedure

In the event of a medical emergency, the PI/designee may require that the blind be broken for the subject experiencing the emergency when knowledge of the subject's treatment assignment may influence the subject's clinical care. Every effort will be made not to unblind the subject unless it is considered absolutely necessary for the welfare of the subject. Prior to unblinding, the investigator is encouraged (to the extent possible, without jeopardizing the subject's health) to contact the Sponsor (or designee) to discuss the decision to break the blind.

Unblinding will occur according to the emergency unblinding SOP, to which there will be 24-

hour access. Documentation of the unblinding event will be captured by the unblinded staff. The PI/designee will be expected to provide a rationale for the necessity of unblinding, based on the expectation that knowledge of the subject's treatment assignment will have a meaningful impact on the subject's medical care in the short term. If a subject's treatment assignment is unblinded, the subject will remain in the study and continue with protocol-defined study visits and procedures, unless there is another reason for subject discontinuation. The decision to unblind will be communicated to all regulatory bodies as required. At the end of the study, documentation of all unblinded subjects (and the rationale for unblinding) will be incorporated into the TMF.

## 4.6. Prior and Concomitant Therapy

All concomitant medications will be recorded in source documents from Visit 1 (Day 1) through Visit 6 (Day 57). After Visit 6, only those concomitant medications associated with AESI, MAAEs, and SAEs will be recorded. If study subjects receive the non-study Covid-19 vaccine after the Visit 5 (Day 43), then details of those vaccinations will be recorded. In case subjects decide to receive non-study Covid-19 vaccine approved by MoH after receiving the study product (after dose 1 and dose 2), it is recommended to be administered 14 days after study vaccination. If they receive non-study Covid-19 vaccine before the Visit 5 (Day 43), these subjects will not be eligible, but study team still contact them for safety follow-up. If study subjects receive non-study Covid-19 vaccine after the Visit 5 (Day 43), they are still in study for safety follow-up; however, the blood samples collected in the Visit 7 (Day 197) will not be included in the Per Protocol Population, but will be analyzed to explore the immunogenicity interaction between study and non-study Covid-19 vaccines. Details on concomitant medications to be recorded include the generic and/or trade name, indication, dosage, regimen, route of administration, and start and end dates of the medication.

The following concomitant medications are prohibited during the study; however, they must not be withheld by the treating physician if clinically indicated to treat a subject:

- Any investigational medicinal product other than the study product
- Administration of immunoglobulins or any blood products
- Administration of any long-acting immune-modifying drugs (e.g., infliximab or rituximab) or the chronic administration (defined as more than 14 days) of immunosuppressive medications (includes systemic corticosteroids at doses equivalent to ≥ 0.5 mg/kg/day of prednisone; the use of topical steroids including inhaled and intranasal steroids is permitted).

Use of any prohibited medication must be recorded in the CRF. Whether a subject who uses a prohibited medication will be included in the Per Protocol Population will be evaluated on a case by case basis.

## 4.7. Treatment Compliance

In Part 2 of this combined Phase 1/2 study, 375 adults aged 18 to ≥ 60 years will be randomized (1:1:1) to comparator vaccine, or one of the two selected doses of COVIVAC, 3 µg (being

evaluated in Phase 1) and 6 µg (an intermediate dose level not tested in the Phase 1, but lower than the maximum tested on the Phase 1 trial). The Phase 2 cohort will follow the same visit schedule, and undergo the same procedures and assessments, as in Phase 1 (except that the V4/D36 visit is conducted by phone/home visit instead of site visit and no blood will be collected for immunogenicity testing on Day 28 (i.e., 4 weeks after the first dose).

## 4.8. Protocol Deviation

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, site SOP requirements, or departure from applicable regulatory requirements. The noncompliance may be either on the part of the subject or the site team/PI.

Major protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, or well-being. Examples of major protocol deviations may include: failure to obtain informed consent, failure to report SAEs, enrolling subjects in violation of key eligibility criteria designed to ensure a specific subject population, or failing to collect data necessary to interpret primary endpoints, as this may compromise the scientific value of the trial.

When appropriate, corrective actions and preventive actions (CAPAs) will be developed by the site to address deviations, and will be implemented promptly. These practices will be consistent with ICH E6 Guidelines.

## 4.9. Safety and Immunogenicity Variables

The following section describes the collection of safety and immunogenicity variables.

### 4.9.1. Safety Variables

#### 4.9.1.1. Reactogenicity Events

Refer to Section 3.3.2

#### 4.9.1.2. Unsolicited Adverse Event

Refer to Section 3.3.3

#### 4.9.1.3. Serious Adverse Event (SAE)

Refer to Section 3.3.8 for the definition of SAE.

#### 4.9.1.4. Severity of Adverse Event

Refer to Section 3.3.9 for the details describing severity.

#### 4.9.1.5. Causality of Adverse Event

Refer to Section 3.3.10 for details on determining causality.

### 4.9.2. Immunogenicity Variables

- The functional (neutralizing) humoral immune response elicited by each formulation of COVIVAC, as measured by a SARS-CoV-2 pseudovirus-based neutralization assay (PNA)
- The Immunoglobulin G (IgG) immune response elicited by each formulation of COVIVAC against the S protein of SARS-CoV-2, as measured by enzyme-linked immunosorbent assay (ELISA)

# 5. SAMPLE SIZE CONSIDERATIONS

This Phase 1/2 study has a two-part selection design with group elimination after the first part (i.e. Phase 1). A total of 25 ($n_1$) subjects per group will be randomized across 4 candidates and one placebo group ($n_1$=20) in the first phase. Assay titers will be analyzed on the log scale. The sample size and power calculations assume an interim analysis will be conducted after D43 of the first phase to eliminate two candidate groups by selecting the two groups with the largest means. Additionally, the observed seroresponse rate (defined as the percentage of subjects in a treatment group with at least a 4-fold rise from baseline in 80% neutralizing antibody titers) will need to be at least 52% at the lower limit of the 95% exact confidence interval. Based on this criterion, there is less than 10% chance of incorrectly failing to consider advancing a vaccine candidate with a true seroresponse rate of 85% or higher, which is estimated to be the minimum response rate that would be consistent with further investment in an additional second-wave COVID-19 vaccine. The Sponsor may consider other factors in selecting the two most suitable candidates to advance to second phase. In the second phase, 125 and 50 ($n_2$) additional subjects will be randomized to the two candidate groups and the placebo group, respectively. The final analysis will be conducted on the full samples from the first and second phase ($n_1 + n_2$).

Safety: Assuming 25 evaluable subjects per group in the first phase (and for elderly subjects enrolled in the second phase) and 150 total subjects ($n_1 + n_2$) in the two candidate groups included in the second phase, the probability of observing at least one serious or severe adverse event by the underlying rate is shown in Table 7 in the protocol. If no events are observed, the upper bound of the exact 95% confidence interval would be 13.7% for the three eliminated groups and 2.4% in the two selected groups.
Immunogenicity: Groups with seroresponse below 52% at the lower limit of the 95% exact confidence interval will not be considered for selection for the second phase. This provides 90% power to correctly advance candidates with a true seroresponse rate ≥85%.

This is a two-stage selection design for selecting the group with the largest mean. Power for selecting the candidate with the largest true mean is driven both by the variability and the smallest difference between the highest mean and the means in the other three candidate groups.

Table 8 in the protocol shows the power to correctly select the candidate with the largest true mean in the first phase (to advance to the second phase) and the overall power for the Phase 1/2 by minimum fold-difference (on the titer scale) between the highest mean and the other means, assuming log10 variability of 0.5. These calculations assume in the first phase there

are $n_1$=22 evaluable subjects in the four candidate groups, two groups are eliminated after the first phase, there are $n_2$=112 additional evaluable subjects in the remaining two candidate groups at D43 of second phase ($n_1 + n_2$=134), and $\mu_4 > \mu_1 = \mu_2 = \mu_3$.

Immunogenicity in Phase 2: The primary objective of Phase 2 is the comparison of COVIVAC 3 µg and COVIVAC 6 µg by the $NT_{50}$ GMT. All calculations assume 10% of subjects will be removed from the per protocol population due to baseline positivity for anti-S IgG or loss to follow up. Superiority of COVIVAC 6 µg will be demonstrated if the lower bound of the 95% CI of the GMT ratio (COVIVAC 6 µg / COVIVAC 3 µg) is >1.0. Table 10 shows the power to demonstrate superiority of one arm over another assuming the log10 variability of $NT_{50}$ is 0.5 (informed by Phase 1 data).

**Table 3: Power for superiority comparison between two arms by GMT ratio where superiority is demonstrated if the lower bound of the 95% CI of the GMT ratio is greater than 1.0. – Protocol Table 10**

| GMT Ratio | Probability Lower Bound >1 (superiority) |
|---|---|
| 1.4 | 58.7% |
| 1.5 | 74.6% |
| 1.6 | 86.1% |
| 1.7 | **93.0%** |
| 1.8 | **96.6%** |

As a secondary objective COVIVAC 3 µg and 6 µg will be compared to AZD1222. The Sponsor may consider a futility analysis based on demonstration of clear inferiority of COVIVAC to AZD1222. Inferiority would be demonstrated if the upper bound of the 95% CI for the GMT ratio (COVIVAC / AZD1222) is less than a stated bound. Table 11 shows the probability to observe an upper bound below 0.5, 0.67, or 0.9 by true GMT ratio. Sequential testing of COVIVAC 6 µg versus AZD1222 followed by COVIVAC 3 µg versus AZD1222 (if inferiority is not shown with 6 µg) will be employed to conserve alpha.

**Table 4: Power to assess inferiority comparison between COVIVAC and AZD1222 where inferiority is demonstrated if the upper bound of the 95% CI of the GMT ratio is less than a stated bound. – Protocol Table 11**

| GMT Ratio, (COVIVAC / AZD1222) | Probability Upper Bound < 0.5 | Probability Upper Bound < 0.67 | Probability Upper Bound < 0.9 |
|---|---|---|---|
| 0.25 | 99.8% | 99.9% | 99.9% |
| 0.4 | 30.8% | 92.6% | 99.9% |
| 0.5 | 2.4% | 49.0% | 96.8% |
| 0.6 | **0.1%** | **11.2%** | **75.1%** |
| 0.7 | **<0.1%** | **0.9%** | **34.6%** |

# 6. GENERAL STATISTICAL CONSIDERATIONS

## 6.1. General Principles

All analyses will be tabulated by vaccination received, including a column for the total across all subjects. Baseline demographics and characteristics, including age, height, weight, sex, race ethnicity, and BMI will be summarized for both the exposed and per protocol populations by treatment group using descriptive statistics (mean, standard deviation, median, 1st and 3rd quartiles, minimum and maximum for continuous and frequencies, percentage, proportions, and exact Clopper-Pearson 95% confidence intervals (CIs) for categorical). All percentages will be presented to one decimal place.

Medical history will be listed and summarized by category. Using the WHO Drug Dictionary, concomitant medications will be tabulated by anatomical therapeutic chemical (ATC) classification, preferred drug name and treatment group. Medical history will be tabulated by MedDRA System Organ Class (SOC), Preferred Term (PT) and treatment group.

Summaries of subject disposition will be prepared for all subjects, including the number and percent of subjects screened, enrolled, study population of full analysis and per protocol, completed and not completed study within each study population, as well as a CONSORT diagram. The reasons for screen failures, abnormal with clinically significant of laboratory results, and COVID-19 associated symptoms will be summarized and listed.

A summary and listing of visit attendance will be prepared, in addition to a summary and listing of study product administration and sample collection/availability for each sample.

## 6.2. Timing of Analyses

An interim analysis of Phase 2 data will be conducted after the last subject of the Phase 2 cohort completes V6 (D57) as the basis for selecting the optimal formulation of COVIVAC to advance to Phase 3 studies.

A final analysis on all safety and immunogenicity data will be performed after the study ends, when all additional safety and immunogenicity data have been collected following the last subject's last study visit (Visit 7, Day 197), and the database is cleaned and locked.

## 6.3. Analysis Populations

### 6.3.1. Enrolled Population

All subjects who provide written informed consent, regardless of the subject's screening, randomization, and treatment status in the study.

### 6.3.2. Exposed Population

All subjects in the enrolled population who were randomized and received at least one vaccination dose (i.e., were accrued).

### 6.3.3. Safety Analysis Population

All subjects in the exposed population for whom any safety data is available. All safety analyses will be performed using this population. The denominators for different safety endpoints may vary according to the number of subjects with available data for the specific endpoint. For instance, the solicited local and systemic adverse event endpoint will be based only on those who have the corresponding CRF data regardless of other safety data. Treatment groups for safety analysis will be assigned according to the actual treatment received.

### 6.3.4. Full Analysis Population

All subjects in the exposed population for whom any post-study product administration immunogenicity results are available. An immunogenicity analysis will also be performed using this population.

### 6.3.5. Per Protocol Population

All subjects in the exposed population who have no major protocol deviations that are determined to potentially interfere with the immunogenicity assessment of the study product.

This population will serve as the primary analysis population for the immunogenicity endpoints. The population will be adapted by time point to include all eligible subjects' data up to the time of disqualifying protocol deviation. The criteria (e.g., intake of prohibited medication expected to influence the immune response) for exclusion of subjects from the per protocol population, and determination of any exclusions based on a blinded review of the data, will be established before database freeze and lock for both interim and final analyses, respectively.

## 6.4. Covariates and Subgroups

In the second interim and final analyses, the candidates that advanced to the second phase will be summarized by phase, age group (18-59 years and ≥60years), and overall.

## 6.5. Missing Data and Outliers

Missing immunogenicity data will not be imputed and will be analyzed as if they were randomly missing. Over the study period, the frequency and percentage of subjects who discontinue from the study will be provided by treatment group. All subjects who discontinue post-randomization will be further described regarding their time to and their reasons for discontinuation. For subjects who discontinue from the study, their data collected before discontinuation will be analyzed under the analysis populations as applicable.

## 6.6. Interim Analyses and Data Monitoring

### 6.6.1. Interim Analysis

Interim analyses will be performed after the last subject in Phase 2 has completed Visit 6 (Day 57) assessments and all the results are available. At the time of the interim analysis, safety

results (unblinded to the DSMB only) and immunogenicity results (unblinded at group level only) will aid in the selection of a single COVIVAC formulation to evaluate in Phase 3. The interim report will include Tables 1-7, 10, 12 ,29 , 31, 32, 34, 36, 37, 41, 42, 43, 62, 80-107 and Figure 12-23 as well as List 7.

### 6.6.2. Data Monitoring

The PI/designee will be responsible for continuous monitoring of all study subjects' safety. In case of urgent need, subjects will have the means to get in contact with study staff at any time (24 hours per day). The PI/designee will also be available by cell phone 24-hours per day for medical emergencies.

Safety will be monitored routinely throughout the study by the PSRT, which includes the PI/designee and other site investigators, the IVAC Clinical Lead, and the Medical Monitor. The PSRT will be continuously involved in safety monitoring and be available to address any urgent medical queries or safety concerns related to any subject's participation in the study. Data management personnel will ensure that the PSRT receives immediate notification of all reported SAEs and any other predefined AEs (e.g., Grade 3 AEs). The PSRT will convene to review blinded safety data on a weekly basis until D43 of the last subject in each phase, then at least once monthly until the end of the study.

During meetings the PSRT will review blinded safety reports and review any outstanding medical or safety queries from the previous review. The blinded safety reports will contain at a minimum, subject disposition and discontinuations, all new Grade 3 and persistent (beyond 6 days post-IP administration) solicited AEs, and all new unsolicited AEs. Cumulative safety data reports will also be made available continuously for review by PSRT members. In addition, the PSRT will review all major protocol deviations in an expedited manner and all other protocol deviations at least on a monthly basis to assess for any potential safety implications, and will provide guidance in the preparation of corrective action plans. The PSRT may also discuss any other study conduct issues that impact study integrity and subject safety, including but not limited to data quality and critical monitoring findings. The PSRT may refer any safety concerns to the DSMB.

A DSMB, composed of at least three independent members with expertise in vaccine clinical trials, will be convened to provide additional safety oversight. In Phase 1, the DSMB will meet to review unblinded safety data through Day 57 (V6), and on the basis of this review provide a recommendation for advancing to Phase 2 (i.e. the DSMB will indicate whether advancement to Phase 2 is warranted based on the reviewed safety data, and whether specific COVIVAC formulations should not be considered for advancement due to safety concerns).

The DSMB will also meet if a study pause rule is met, or the PSRT elects to implement a study pause. If this occurs, no further enrollment will occur, and no study product will be administered until the DSMB approves lifting the pause based on unblinded review of all safety data accrued during the trial. If the study is permanently terminated, subjects who have already received study product will continue with all scheduled protocol visits and assessments; however, they will not receive any further study product.

DSMB reviews will indicate whether or not safety concerns were identified, and whether the trial should continue without change, be modified, or be terminated. The Sponsor will carefully consider the DSMB recommendations. If the Sponsor does not agree with these recommendations, a meeting will be held between the Sponsor, PI, and DSMB to reach consensus on the appropriate action(s) to take in regard to the trial. However, if attempts to reach consensus fail, the Sponsor's opinion will prevail. In such situations, the Sponsor will inform the MoH and NIHE's EC of the Sponsor's perspective, and any changes to the trial. The PSRT, PI or IVAC Clinical Lead may also seek additional guidance from the DSMB as dictated by the occurrence of certain events that do not warrant a study pause.

## 6.7. Multicenter Studies

Not applicable, Phase 2 is a single center study.

## 6.8. Multiple Comparisons/Multiplicity

As the two-stage selection design relies on ranking of GMTs, not testing of differences between candidate groups, no adjustment for multiplicity will be performed.

# 7. STUDY PARTICIPANTS

## 7.1. Disposition of Participants

Summaries of subject disposition will be prepared for all subjects, including the number and percent enrolled, screened, randomized, and administered study product (Table 7), as well as a CONSORT diagram (Figure 1) describing study participation and discontinuation. The reasons for screen failures and discontinuations will be summarized and listed (Table 8, Listing 1).

## 7.2. Protocol Deviations

A summary of subject-specific protocol deviations will be presented by study group in the exposed population. The reasons for the deviation will be also included (Table 6, Listing 2). Protocol deviation may lead to exclusion from the PP population. The summary of analysis population will be presented by study group and visit (Table 9).

# 8. SAFETY EVALUATION

## 8.1. Demographic and Other Baseline Characteristics

Baseline demographics and characteristics, including age, height, weight, sex, race, ethnicity, and BMI will be summarized for both the exposed and per protocol populations by treatment group using descriptive statistics (mean, standard deviation, median, 25$^{th}$ and 75$^{th}$ quartiles, minimum and maximum for continuous and rates for categorical). Summary tables will be separated by type of data as continuous and categorical (See Table 10 through Table 13). A listing of individual demographics will be provided (Listing 3).

### 8.1.1. Medical History

Medical history will be tabulated by MedDRA System Organ Class (SOC), Preferred Term

(PT) and treatment group (Table 14 through Table 16, Listing 4).

### 8.1.2. Concomitant Medications

Using the WHO Drug Dictionary, concomitant medications will be tabulated by anatomical therapeutic chemical (ATC) classification, preferred drug name and treatment group (Table 110). Individual subject listing will be prepared for all concomitant medications (Listing 5).

## 8.2. Measurements of Visit Compliance and Research Sample Collection

A summary of the number of subjects completing each scheduled visit and the number providing research sample results at each visit will be prepared (Table 17).

## 8.3. Adverse Events

All safety assessment will take place in the safety analysis population, according to the treatment received. All subject-level percentages (solicited/unsolicited AEs, clinical safety laboratory abnormalities, etc.) will be supplemented with two-sided 95% CIs computed via the Clopper-Pearson method. Individual summaries (denominators for percentages) will be limited to the number of subjects with the appropriate analysis population with the data available for analysis for the given endpoint. Summaries will be provided overall by group and separately in adults aged 18-59 years and ≥60 years (Tables 41-1, Table 43-1 and Table 44-1).

The non-serious adverse events from combined solicited and unsolicited (excluding serious adverse event) that being reported during the first 28 days after each vaccination will be summarized with the number of subject by vaccination groups. This combined data will be summarized by System Organ Class (SOC) and Preferred Term (PT) also (Tables 42-1).

### 8.3.1. Solicited Events and Symptoms

Solicited local and systemic adverse events: Percentages of subjects experiencing each solicited AE within 30 minutes observation period and during the first 7 days after each dose vaccination will be presented for each symptom (Tables 30, Tables 32, Table 32-1, Table 35, Table 37 and Table 37-1). All solicited AEs will also be summarized according to defined severity grading scales (Table 31, Table 31-1, Table 31-2, Table 33, Table 33-1, Table 33-2, Table 36, Table 36-1, Table 36-2, Table 38, Table 38-1 and Table 38-2). Comparison of solicited AE of different dose levels will be done for overall dose, first dose and second dose of each symptom. Data listings of all solicited AEs will be provided by subject (Listing 6).

### 8.3.2. Unsolicited Adverse Events

Overall number of subjects with adverse events after any dose of vaccination in safety analysis population will be summarized in Table 41 and Table 41-1. Overall number of subject experiencing unsolicited AEs, including SAEs, onset during the first 28 days after each dose vaccination will be summarized by vaccine groups and relatedness (Tables 43 and table 43-1). Number of subject experiencing SAEs throughout the entired study period will also be presented (Tables 44 and Table 44-1). All unsolicited AEs with onset during the first 28 days

following each dose administration will be assessed for severity and as either related or not related to study product by the investigator (Tables 58, Table 58-1, Table 58-2 and Tables 59).

AESI, MAAEs, and SAEs: All AESI, MAAEs, and SAEs through Visit 7 (Day 197) will be recorded and the number, severity, and relatedness to study product will be summarized (Tables 46 through Tables 50). Subject-wise data listing for all unsolicited AEs will be provided (Listing 7).

When an AE occurs more than once for a subject, the subject will be counted only once for the corresponding PT according to the maximum severity of the events.

Medically-attended adverse events (MAAEs) are unsolicited AEs for which the subject received medical attention, such as during an emergency room visit or a visit to or from medical personnel (e.g., medical doctor).

Adverse events of special interest (AESIs) for this study include:

- Potential immune-mediated medical condition (PIMMC), given that vaccination has been associated with autoimmunity
- AEs associated with COVID-19, given the importance of subject safety of managing any occurrence of COVID-19, and the possible association of vaccination with enhancement of COVID-19

## 8.4. Deaths, Serious Adverse Events and Other Significant Adverse Events

A listing of all data related to deaths, SAEs and other significant AEs will be presented (See Appendix 3., Listing 8).

## 8.5. Clinical Laboratory Evaluations

No clinical laboratory evaluations will be performed in Phase 2 part of the study.

## 8.6. Vital Signs and Physical Evaluations

Vital sign measurements including systolic and diastolic blood pressure (mmHg), temperature (°C), pulse (beats/min) and respiratory rate (breaths/minute) will be assessed at each visit, including change from pre-first vaccination and pre-second vaccination (Table 62 through Table 73). Vital signs will be tabulated by visit and vaccination group, including mean, standard deviation, median and range. A full listing will be prepared (Listing 9, Appendix 3) and will include study visit, value, units and change from baseline.

Physical exam results, including number and proportion of participants with abnormalities, will be summarized for the safety analysis population and presented in Appendix 1.G. (Table 74 through Table 81), by vaccination group. A full listing will be prepared (Listing 10, Appendix 3).

# 9. IMMUNOGENICITY

The analysis of immunogenicity will be performed on the per protocol population as the primary analysis and the full analysis population as a secondary analysis. Analyses described below will be summarized in the interim analyses for all subjects included in the phase 2 part of the study. Relative endpoints derived from Geometric Mean Fold Rise (GMFR) will include all subjects from the per protocol population. Absolute endpoints such as those derived from the Geometric Mean Titer (GMT) will exclude baseline seropositive subjects (i.e., subjects with anti-S IgG antibody titer ≥ LLOQ of the assay at baseline).

Immunogenicity data will be descriptively summarized including the mean, SD, median, range (min and max), GMT, and 95% CI for the GMT with one-half the lower limit of quantification (LLOQ) and with the upper limit of quantification (ULOQ) used as the observed value, whenever these limits are met. For estimation of the GMT, GMT ratio, and corresponding confidence limits, analyses will incorporate censoring where appropriate and log-scale coefficients will be back-transformed in order to compute the estimate and corresponding confidence limits for the relevant quantity. GMFRs will be computed using estimates of the log difference of the paired samples, with corresponding CIs computed via the *t*-distribution, utilizing the antilog transformation to present the ratio. Analyses of binary variables will include 95% CIs computed via the Clopper-Pearson method. Additionally, the distribution of the titers will be summarized using reverse cumulative distribution curves (Figure 14 through Figures 17).

The immunogenicity analysis part will be summarized in term of GMT ratio comparing between vaccination groups for overall population and by age group (18-59 years and ≥60 years). (Tables 86 through Tables 87 and Tables 96 through Tables 97).

## 9.1. $NT_{50}$ against SARS-CoV-2 Pseudovirus

The pseudovirus neutralization assay (PNA) will be used to quantify the functional humoral immune response against SARS-CoV-2 by measuring the 50% neutralizing titer ($NT_{50}$) against a SARS-CoV-2 pseudovirus in Phase 2.

The results generated from the central laboratory (NEXELIS, Canada) for SARS-CoV-2 PNA will be reported with titer units "$NT_{50}$". A correlation factor of 1/1.872 will be applied to convert the reported results from $NT_{50}$ titer to IU/mL which is the assigned unit for WHO International Standard.

The following formula shall be used for converting $NT_{50}$ titer to IU/mL:

**Result (IU/mL) = Result ($NT_{50}$ titer)/ 1.872**

The $NT_{50}$ GMT against SARS-CoV-2 pseudovirus will be described along with its 95% CI at baseline (D1), 14 days (D43) and 6 months (D197) after the second vaccination in subjects who are anti-S IgG seronegative (i.e., anti-S IgG value less than LLOQ of the assay) at baseline by age group (18-59 years and ≥ 60 years), and overall. (Table 82 and Table 84, Appendix 1). The $NT_{50}$ will also be described via the geometric mean concentration (GMC) in IU/mL along with the its 95% CI at D1, D43 and D197 (Table 83 and Table 85).

The GMT ratio with 95% CI for pairwise comparison of $NT_{50}$ GMT values between vaccination groups will be presented at 14 days and 6 months after the second vaccination for each pair (Tables 86, Tables 87).

The GMFR from baseline in $NT_{50}$ against SARS-CoV-2 pseudovirus at 14 days and 6 months after the second vaccination will be calculated along with its 95% CI for each study group (Tables 88 and Tables 89, Appendix 1).

Number and percentage (with 95% CI) of subjects with $NT_{50}$ seroresponses against SARS-CoV-2 pseudovirus as defined by (1) a ≥ 4-fold increase from baseline, and (2) a ≥ 10-fold increase from baseline at 14 days and 6 months after the second vaccination will be summarized at each time point for each study group (Table 90 through Table 93, Appendix 1).

Phase 2 will include the following additional summaries:

- GMT/C ratios and 95% CIs of $NT_{50}$ comparing COVIVAC groups
- GMT/C ratios and 95% CIs of $NT_{50}$ comparing COVIVAC groups to AZD1222

## 9.2. Anti-S IgG Assessed by ELISA

Anti-S IgG antibody titers will be measured by ELISA assay which detects IgG antibodies to the full-length pre-fusion Spike protein of SARS-CoV-2.

Serum antibody concentration will be reported from the central laboratory (NEXELIS, Canada) in ELISA Units (ELU)/mL. A correlation factor of 1/7.9815 will be applied to convert the reported results from ELU/mL to Binding Antibody Units (BAU)/mL which is the assigned unit for WHO International Standard.

The following formula shall be used for converting concentration units from ELU/mL to BAU/mL:

**Result (BAU/mL) = Result (ELU/mL)/ 7.9815**

Anti-S IgG antibody results will be summarized at baseline, 14 days and 6 months after the second study injection. The summarization of the anti-S IgG antibody titers will be performed for the overall and age group (18-59 years and ≥ 60 years).

The summarization will include GMCs with 95% CIs, including baseline (Tables 94 and Tables 95, Appendix 1), GMC ratio with 95% CI for pairwise comparison between vaccine groups (Tables 96, Tables 97, Appendix 1), GMFR from baseline with 95% CI (Tables 98, Tables 99, Appendix 1), and percent of subjects with ≥ 4-fold and ≥ 10-fold increase in the anti-S IgG antibody titers compared with baseline (Tables 100 through Tables 103, Appendix 1).

Phase 2 will include the following additional summaries:

- GMC ratios and 95% CIs of anti-S IgG comparing COVIVAC groups
- GMC ratios and 95% CIs of anti-S IgG comparing COVIVAC groups to AZD1222

### 9.3. The S protein-specific T cell

The S protein-specific T cell response elicited by each of two selected COVIVAC formulations will be measured via ELISpot assay at baseline, 14 days, and 6 months after the second vaccination in a subset of subjects enrolled in the second phase of the study. The magnitude, phenotype, and cytokine-expressions pattern of S protein-specific T cells will be descriptively analyzed by timepoint (absolute and relative to baseline) by vaccination groups. To assess the S protein-specific T cell response elicited by each of two selected COVIVAC formulations, as measured by enzyme-linked immunospot assay (ELISpot), at baseline, and 14 days and 6 months after the second vaccination, in a subset of adults aged 18-59 years and ≥ 60 years.
The median at baseline The S protein-specific T cell at 14 days and 6 months after the second vaccination will be calculated along with its 95% CI for each study group (Table 104 through Table 109, Appendix 1J).

## 10. REPORTING CONVENTIONS

P-values will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.001" and p-values greater than 0.999 will be reported as ">0.999". Means and medians will be presented to one decimal place more than the raw value, standard deviations and confidence intervals will be presented to 2 extra decimals. Percentages will be reported to one decimal and corresponding 95% CIs will be to two decimals. Percentages less than 0.1% (or <0.01%) will be reported as "<0.1" (or "<0.01"), percentages >99.9% (or >99.99%) will be reported as ">99.9" (">99.99") and 100% will be reported as "100".

## 11. TECHNICAL DETAILS

SAS version 9.4 will be used to generate all tables, figures and listings.

## 12. SUMMARY OF CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

For SARS-CoV-2 PNA, $NT_{50}$ will be determined based on the dilution of serum required to achieve 50% reduction in relative luminescence units (RLU) value compared to pseudoparticle control. The results generated from the central laboratory will be reported with titer units "$NT_{50}$". In order to covert the reported values from the laboratory to be according to the WHO International Standard, a correlation factor of 1/1.872 will be applied to convert the reported results from $NT_{50}$ titer to GMC in IU/mL which is the assigned unit for WHO International Standard. Hence, data analyses for PNA $NT_{50}$ results will be expressed in IU/mL.

Anti-S IgG antibody titers will be measured by ELISA assay which detects IgG antibodies to the full-length pre-fusion Spike protein of SARS-CoV-2. According to the study endpoints, serum antibody concentration will be reported from the central laboratory in ELISA Units (ELU)/mL. A correlation factor of 1/7.9815 will be applied to convert the reported results from ELU/mL to Binding Antibody Units (BAU)/mL which is the assigned unit for WHO International Standard. Hence, data analyses for anti-S IgG results will be expressed in

BAU/mL.

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# APPENDIX 1. TABLES

## LIST OF TABLES

# Appendix 1.A. Characteristics at Screening

Tables copied from the protocol:

**Table 1: Treatment Groups - Protocol Table 3 (see Table 1 in Section 4.1.)**

**Table 2: Visit Schedule (see Table 2 in Section 4.1.)**

**Table 3: Power for superiority comparison between two arms by GMT ratio where superiority is demonstrated if the lower bound of the 95% CI of the GMT ratio is greater than 1.0. – Protocol Table 10 (see Table 3 in Section 5.)**

**Table 4: Power to assess inferiority comparison between COVIVAC and AZD1222 where inferiority is demonstrated if the upper bound of the 95% CI of the GMT ratio is less than a stated bound. – Protocol Table 11 (see Table 4 in Section 5.)**

## Table 5: Schedule of Study Visits and Procedures – Protocol Table 5

| VISIT | Screen | V1 | V2 | V3 | V4[K] | V5 | V6 | V7 |
|---|---|---|---|---|---|---|---|---|
| Study Day (allowed window in days) | **-42 to 1** | **1** | **8 (+3)** | **29 (+3)** | **36 (+3)** | **43 (+3)** | **57 (+7)** | **197 (+14)** |
| Informed consent | ✓ | | | | | | | |
| Demographics | ✓ | | | | | | | |
| Medical History | ✓ | | | | | | | |
| Concomitant medications[A] | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Eligibility check | ✓ | | | ~ | | | | |
| Vital signs | ✓ | ✓^✓ | ✓ | ✓^✓ | ✓ | ✓ | ✓ | ✓ |
| Complete physical exam | ✓ | | | | | | | |
| Targeted physical exam[B] | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Clinical chemistry[C] | ✓ | | ✓ | | ✓ | | | |
| Hematology[D] | ✓ | | ✓ | | ✓ | | | |
| Viral serology tests[E] | ✓ | | | | | | | |
| Urine pregnancy test[F] | ✓ | ✓ ✓ | | ✓ | | | | |
| Unsolicited AEs[G] | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Concomitant medications[H] | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Randomization | | ✓ | | ~ | | | | |
| Blood for humoral immunity | | ✓ | | ✓* | | ✓ | | ✓ |
| Blood for CMI[I] | | ✓ | | | | ✓ | | ✓ |
| Administer study product | | ✓ | | ✓ | | | | |
| Observation/solicited AEs | | ✓ | | ✓ | | | | |
| Provide Diary Card | | ✓ | | ✓ | | | | |
| Review Diary Card | | | ✓ | | ✓ | ✓[K] | | |
| Exit study | | | | | | | | |
| Blood volumes (mL): | | | | | | | | |
| Safety laboratory tests (Phase 1 only) | 4 | | 4 | | 4 | | | |
| HBV and HCV screening | 2 | | 0 | | 0 | | | |
| Humoral immunity | | 10 | | 10 | | 10 | | 10 |
| Cell-mediated immunity | | 16 | | | | 16 | | 16 |

~ Confirmation
^ Evaluations will be conducted twice – before and after vaccination
* Only in Phase 1
[A] After Visit 6, only medications associated with an AESI, MAAE or SAE will be recorded.
[B] Targeted PE will be conducted only in the event of new symptom, sign or, until Visit 6, any new AE; or, after Visit 6, any new AESI, MAAE or SAE.
[C] Serum creatinine, ALT, AST, total bilirubin; only in Phase 1.
[D] WBC count, hemoglobin, platelets; only in Phase 1.
[E] HBsAg, HCV Ab, only in Phase 1
[F] Women of childbearing potential (WOCBP) only
[G] After Visit 6, only AESI, MAAEs, and SAEs will be recorded.
[H] After Visit 6, only concomitant medications associated with a newly reported AESI, MAAE or SAE will be recorded
[I] Only in subset of subjects in Phase 2
[K] In Phase 1 the diary card will be reviewed at Visit 4 (Day 36). In Phase 2, study staff will make a phone call/home visit to remind subjects to complete the diary card at Visit 4 (Day 36), and the diary card will be

collected and reviewed at Visit 5 (Day 43) (2 weeks after vaccination)

***Note:*** *The study dates of follow-up visits after the V3/D29 visit will be adjusted according to the actual date of the V3/D29 visit.*

Remark: 1 month = 28 days (4 weeks)

**Table 6: Distribution of Protocol Deviations by Category, Type and Study Group**

| Category | Deviation Type | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) | n (%) | n (%) | n (%) |
| Eligibility/enrollment | Any type | | | | |
| | Did not meet inclusion/exclusion criteria but enrolled | | | | |
| | Informed consent not taken | | | | |
| | Incorrect informed consent process | | | | |
| | Other | | | | |
| Vaccination procedure | Any type | | | | |
| | Randomized to wrong treatment arm: Dosed with wrong treatment arm at V1 | | | | |
| | Wrong treatment arm administered at 2nd dose | | | | |
| | Dosed when withdrawal/discontinuation criteria were met | | | | |
| | Incorrect vaccination procedure | | | | |
| | Damaged/ expired IP/ quarantined kit used without prior approval | | | | |
| | Missed 2nd dose vaccine administration | | | | |
| | Randomized to wrong age group | | | | |
| | Other | | | | |
| Missed procedures | Any type | | | | |
| | Pre-vaccination blood sample missed to be collected from eligible subject but subject continued in the study | | | | |
| | Post-vaccination blood sample missed to be collected from eligible subject | | | | |
| | Assessmens at scheduled visits were not performed | | | | |
| | Post-vaccination assessment missed | | | | |
| | Other | | | | |

**Table 6: Distribution of Protocol Deviations by Category, Type and Study Group (continued)**

| Category | Deviation Type | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) | n (%) | n (%) | n (%) |
| Visit window | Any type | | | | |
| | Out of window visit | | | | |
| | Missed visit/ visit not conducted | | | | |
| | Missed vaccine administration | | | | |
| | Delayed vaccine administration | | | | |
| | Other | | | | |
| etc. | etc. | | | | |

**Note**: Number of subjects in the safety analysis population

## Table 7: Subject Disposition by Study Group

| Status | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) | n (%) | n (%) | n (%) |
| **Screened** | xxx | NA | NA | NA |
| **Not eligible** | xxx | | | |
| **Eligible** | xxx | | | |
| **Not randomized** | xxx | | | |
| **[Reason 1]** | xxx | | | |
| **[Reason 2]** | xxx | | | |
| **[etc.]** | xxx | | | |
| **Randomized** | xxx | | | |
| **Received 1st dose vaccination** | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Received 2nd dose vaccination** | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Completed Day 29 visit** | | | | |
| **Completed Day 57 visit** | | | | |
| **Completed the study** | | | | |
| **Not completing the study** | | | | |
| **Reason for not completing the study**<br>- Serious adverse event | | | | |
| - Non-serious adverse event | | | | |
| - Protocol deviation | | | | |
| - Consent withdrawal | | | | |
| - Migrated / Moved from the study area | | | | |
| - Lost to follow-up | | | | |
| - Other reason | | | | |
| **Safety analysis population** | | | | |
| **Full analysis population** | | | | |
| **Per protocol population** | | | | |
| - Baseline (D1) | | | | |
| - 28 days after the first vaccination (D29) | | | | |
| - 14 days after the second vaccination (D43) | | | | |
| - 6 months after the second vaccination (D197) | | | | |

**Note:** "xx" represent the value number.
"xx.x %" is the percentage calculated from total number of 1st dose vaccinated subjects (N).

## Table 8: Summary of Screen Failures

| Inclusion/Exclusion Category | Inclusion/Exclusion Criterion | n[a] (%[b]) |
|---|---|---|
| Inclusion and Exclusion | Number of subjects failing any eligibility criterion | |
| Inclusion | Any inclusion criteria<br>1. Adult ≥18 and ≥ 60 years of age inclusive at the time of randomization<br>2. Having no clinically significant acute medical condition, and no chronic medical condition that has not been controlled within 90 days of randomization, as determined by medical history, physical examination, screening laboratory test results,<br>3. Has provided written informed consent prior to performance of any study-specific procedure<br>4. Has a body mass index (BMI) of 17 to 40 kg/m2, inclusive, at screening<br>5. Resides in study site area and is able and willing to adhere to all protocol visits and procedures<br>6. If a woman is of childbearing potential age, must not be breastfeeding or be pregnant (based on a negative urine pregnancy test at screening and during the 24 hours prior to receipt of the first dose of IP), must plan to avoid pregnancy for at least 28 days after the last dose of IP, and be willing to use an adequate method of contraception consistently and have a repeated pregnancy test prior to the second (last) dose of IP | |
| Exclusion | Any exclusion criteria<br>1.Use of any investigational medicinal product within 90 days prior to randomization or planned use of such a product during the period of study participation<br>2. History of administration of any non-study vaccine within 28 days prior to administration of study vaccine or planned vaccination within 3 months after enrolment Note: receipt of any COVID-19 vaccine that is licensed or granted Emergency Use Authorization in Vietnam during the course of study participation is not exclusionary if administered after Visit 5.<br>3. Previous receipt of investigational vaccine for SARS or MERS, or any investigational or licensed vaccine that may have an impact on interpretation of the trial results<br>4. History of hypersensitivity reaction to any prior vaccination or known hypersensitivity to any component of the study vaccine<br>5. History of egg or chicken allergy<br>6. History of angioedema<br>7. History of anaphylaxis (≥ grade 2)<br>8. Acute illness (moderate or severe) and/or fever (body temperature measured orally ≥38°C)<br>9. Any abnormal vital sign deemed clinically relevant by the PI<br>10. Abnormality in screening laboratory test deemed exclusionary by the PI in consultation with the Sponsor<br>11. History of confirmed HIV<br>12. History of laboratory-confirmed COVID-19<br>13. History of malignancy, excluding non-melanoma skin and cervical carcinoma in situ | |

## Table 8: Summary of Screen Failures (continued)

| Inclusion/Exclusion Category | Inclusion/Exclusion Criterion | n[a] (%[b]) |
|---|---|---|
| Exclusion | 14. Any confirmed or suspected immunosuppressive or immunodeficient state<br>15. Administration of immunoglobulin or any blood product within 90 days prior to first study injection or planned administration during the study period<br>16. Administration of any long-acting immune-modifying drugs (e.g., infliximab or rituximab) or the chronic administration (defined as more than 14 days) of immunosuppressants within six months prior to first study injection, or planned administration during the study period (includes systemic corticosteroids at doses equivalent to ≥ 0.5 mg/kg/day of prednisone; the use of topical steroids including inhaled and intranasal steroids is permitted)<br>17. History of known disturbance of coagulation or blood disorder that could cause anemia or excess bleeding. (e.g, thalassemia, coagulation factor deficiencies)<br>18. Recent history (within the past year) or signs of alcohol or substance abuse<br>19. Any medical, psychiatric or behavior condition that in the opinion of the PI may interfere with the study objectives, pose a risk to the subject, or prevent the subject from completing the study follow-up<br>20. Employee of any person employed by the Sponsor, the contract research organization (CRO), the PI, study site personnel, or site | |

**Note**: [a] More than one criteria may be marked per subject.

[b] Denominator for percentages is the total number of screen failures.

## Table 9: Analysis Populations by Study Group and Visit

| Visit | Reason subjects excluded | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Total vaccinated population** [1] | | | | | |
| | Number vaccinated | | | | |
| | Number not vaccinated | | | | |
| | [Reason 1] | | | | |
| | [Reason 2] | | | | |
| | [etc.] | | | | |
| **Per protocol population** [2] | | | | | |
| Baseline (D1) | Included | | | | |
| | Excluded | | | | |
| | [Reason excluded] | | | | |
| | [etc.] | | | | |
| 28 days after the first vaccination (D29) | Included | | | | |
| | Excluded | | | | |
| | [Reason excluded] | | | | |
| | [etc.] | | | | |
| 14 days after the second vaccination (D43) | Included | | | | |
| | Excluded | | | | |
| | [Reason excluded] | | | | |
| | [etc.] | | | | |
| 6 months after the second vaccination (D197) | Included | | | | |
| | Excluded | | | | |
| | [Reason excluded] | | | | |
| | [etc.] | | | | |
| etc. | | | | | |

N = Number of participant in Enrolled population.

[1] Denominator for percentage is N. [2] Denominator for percentage is number vaccinated.

**Table 10: Summary of Categorical General Characteristics at Screening, Exposed Population**

| Characteristics | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Sex, n (%)** | | | | |
| Male | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Female | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Race, n (%)** | | | | |
| Asian | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Other | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Ethnicity, n (%)** | | | | |
| Kinh | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Other | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note:** "xx" represent the value number.

**Table 11: Summary of Categorical General Characteristics at Screening, Per Protocol Population**

| Characteristics | All (N=xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|
| | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| **Sex, n (%)** | | | | |
| Male | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Female | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Race, n (%)** | | | | |
| Asian | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Other | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Ethnicity, n (%)** | | | | |
| Kinh | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Other | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note:** "xx" represent the value number.

**Table 12: Summary of Continuous General Characteristics at Screening, Exposed Population**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Age (years)** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Weight (kg)** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Height (cm)** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **BMI (kg/m$^2$)** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |

**Note:** "xx" represent the value number.

**Table 13: Summary of Continuous General Characteristics at Screening, Per Protocol Population**

| | All (N=xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|
| | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| **Age (years)** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Weight (kg)** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Height (cm)** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **BMI (kg/m$^2$)** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |

**Note:** "xx" represent the value number.

**Table 14: Overall Number of Subjects at Least One Medical History by System Organ Class (SOC) and Preferred Term (PT)**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| All SOC | All PT | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| SOC 1 | All | | | | |
| | PT 1 | | | | |
| | PT 2 | | | | |
| | ….. | | | | |
| SOC 2 | All | | | | |
| | PT 1 | | | | |
| | PT 2 | | | | |
| | …… | | | | |

**Note**: "xx" represent the value number.
"N" represent the number of subject who has at least one medical history.

**Table 15: Number of Subjects with Past Medical History by System Organ Class (SOC) and Preferred Term (PT)**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| All SOC | All PT | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| SOC 1 | All | | | | |
| | PT 1 | | | | |
| | PT 2 | | | | |
| | ….. | | | | |
| SOC 2 | All | | | | |
| | PT 1 | | | | |
| | PT 2 | | | | |
| | …… | | | | |

**Note**: "xx" represent the value number.
"N" represent the number of subject who has at least one medical history.

**Table 16: Number of Subjects at Least One Current Medical History by System Organ Class (SOC) and Preferred Term (PT)**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| All SOC | All PT | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| SOC 1 | All | | | | |
| | PT 1 | | | | |
| | PT 2 | | | | |
| | ….. | | | | |
| SOC 2 | All | | | | |
| | PT 1 | | | | |
| | PT 2 | | | | |
| | …… | | | | |

**Note**: "xx" represent the value number.
"N" represent the number of subject who has at least one medical history.

**Table 17: Summary of Visit Attendance and Sample Collection[1], Exposed Population**

| Day | Study Visit | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Screening** | **1[2]** | **8** | **29[2]** | **36** | **43** | **57** | **197** |
| **Completed visits** | | | | | | | | |
| 3 µg (N = 125) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| 6 µg (N = 125) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| AstraZeneca (N = 125) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| All (N=375) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **Functional humoral immune response by PNA** | | | | | | | | |
| 3 µg (N = 125) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) |
| 6 µg (N = 125) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) |
| AstraZeneca (N = 125) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) |
| All (N=375) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) |
| **Anti-S IgG response by ELISA** | | | | | | | | |
| 3 µg (N = 125) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) |
| 6 µg (N = 125) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) |
| AstraZeneca (N = 125) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) |
| All (N=375) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) | | xx (xx.x %) |

**Note**: N = number of participants in the safety analysis population.

[1] Samples collected and assay results available.

[2] Vaccination day

Data are only expected at visits indicated by x (%).

**Table 18: Solicited Injection Site and Systemic Reactions Toxicity Grading Table- Protocol Appendix 1**

| Reaction to Injectable Product | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| **Pain/ Tenderness** | Does not interfere with activity | Some interference with activity OR Repeated use of non-narcotic pain reliever > 24 hours | Significant; prevents daily activity OR Any use of narcotic pain reliever | Emergency room (ER) visit or hospitalization |
| **Erythema[a]** | 2.5 – 5 cm | 5.1 – 10 cm | > 10 cm and/or ulceration OR secondary infection OR phlebitis OR sterile abscess OR drainage | Necrosis or exfoliative dermatitis |
| **Swelling/ Induration[a]** | 2.5 – 5 cm and does not interfere with activity | 5.1 – 10 cm OR Interferes with activity | > 10 cm OR prevents daily activity and/or ulceration OR secondary infection OR phlebitis OR sterile abscess OR drainage | Necrosis |
| **Temperature (oral)** | 38.0 – 38.4°C 100.4 – 101.1°F | 38.5 – 38.9°C 101.2 – 102.0°F | 39.0 – 40°C 102.1 – 104°F | > 40°C > 104°F |
| **Headache** | No interference with activity | Some interference with activity OR Repeated use of nonnarcotic pain reliever >24 hours | Significant; prevents daily activity OR Any use of narcotic pain reliever | ER visit or hospitalization |
| **Fatigue/ Malaise** | No interference with activity | Some interference with activity | Significant; prevents daily activity | ER visit or hospitalization |
| **Myalgia** | No interference with activity | Some interference with activity | Significant; prevents daily activity | ER visit or hospitalization |
| **Arthralgia** | No interference with activity | Some interference with activity | Significant; prevents daily activity | ER visit or hospitalization |
| **Nausea/ Vomiting** | No interference with activity | Some interference with activity | Prevents daily activity OR Requires outpatient IV hydration | ER visit or hospitalization for hypotensive shock |

[a] For erythema and swelling/induration, longest diameter should be noted in centimeters. Swelling/induration should be evaluated and graded using the functional scale as well as the actual measurement.

The grading scales for local and systemic AEs have been derived from *Guidance for Industry, Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials*, U.S. Department of Health and Human Services, FDA, CBER, September 2007 (https://www.fda.gov/media/73679/download) and the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (Version 2.1, July 2017) from the US NIH (https://rsc.niaid.nih.gov/sites/default/files/daidsgradingcorrectedv21.pdf).

## Table 19: Vital Signs Toxicity Grading – Protocol Appendix 2

| Vital Signs[a] | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| **Tachycardia – beats per minute** | 101 – 115 | 116 – 130 | > 130 | Hospitalization for arrhythmia |
| **Bradycardia – beats per minute[b]** | 50 – 54 | 45 – 49 | < 45 | ER visit or hospitalization for arrhythmia |
| **Hypertension (systolic) – mm Hg** | 141 – 150 | 151 – 165 | > 165 | ER visit or hospitalization for malignant hypertension |
| **Hypertension (diastolic) – mm Hg** | 91 – 99 | 100 – 105 | > 105 | ER visit or hospitalization for malignant hypertension |
| **Hypotension (systolic) – mm Hg** | 85 – 89 | 80 – 84 | < 80 | ER visit or hospitalization for hypotensive shock |
| **Respiratory Rate – breaths per minute** | 21 – 23 | 24 – 27 | > 27 | Intubation |

[a] Subject should be at rest for all vital sign measurements.
[b] Grade 1 bradycardia or grade 1 tachypnea will not be considered an abnormality for this study, unless judged to be clinically significant by the PI in consultation with the Sponsor.

The grading scales for abnormal vital signs have been derived from *Guidance for Industry, Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials*, U.S. Department of Health and Human Services, FDA, CBER, September 2007.

## Table 20: Serum Toxicity Grading – Protocol Appendix 3

| Serum | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Creatinine (mg/dL) | 1.1 – 1.3 x ULN | > 1.3 – 1.8 x ULN OR increase of > 0.3 above baseline | > 1.8 – < 3.5 x ULN OR increase of 1.5 – < 2.0 x above baseline | ≥ 3 .5 x ULN OR increase of > 2.0 x above baseline |
| Liver function tests – AST, ALT increased | 1.25 – < 2.5 x ULN | 2.5 – <5.0 x ULN | 5.0 – < 10.0 x ULN | ≥ 10.0 x ULN |
| Total bilirubin | 1.1 – < 1.6 x ULN | 1.6 – < 2.6 x ULN | 2.6 – < 5.0 x ULN | ≥ 5.0 x ULN |

Abbreviation: ULN = upper limit of normal range

Note: the laboratory values provided in this table serve as guidelines and are dependent upon institutional normal parameters.

The grading scales for laboratory abnormalities have been derived from *Guidance for Industry, Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials*, U.S. Department of Health and Human Services, FDA, CBER, September 2007, and the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (Version 2.1, July 2017) from the US NIH.

## Table 21: Hematology Toxicity Grading – Protocol Appendix 3

| Hematology | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Hemoglobin [Female] (g/dL) | 11.0 – 12.0 | 9.5 – 10.9 | 8.0 – 9.4 | < 8.0 |
| Hemoglobin [Male] (g/dL) | 12.5 – 13.5 | 10.5 – 12.4 | 8.5 – 10.4 | < 8.5 |
| OR Hemoglobin, change from baseline value (g/dL) | 1.0 – 1.5 | 1.6 – 2.0 | 2.1 – 5.0 | > 5.0 |
| WBC, increased (cell/$mm^3$) | 10,800 – 15,000 | 15,001 – 20,000 | 20,001 – 25,000 | > 25,000 |
| WBC, decreased (cell/$mm^3$) | 2,500 – 3,400 | 1,500 – 2,499 | 1,000 – 1,499 | < 1,000 |
| Platelets, decreased (cell/$mm^3$) | 100,000 – <125,000 | 50,000 – < 100,000 | 25,000 – < 50,000 | < 25,000 |

Abbreviation: ULN = upper limit of normal range

Note: the laboratory values provided in this table serve as guidelines and are dependent upon institutional normal parameters.

The grading scales for laboratory abnormalities have been derived from *Guidance for Industry, Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials*, U.S. Department of Health and Human Services, FDA, CBER, September 2007, and the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (Version 2.1, July 2017) from the US NIH.

## Table 22: Vital Signs at Screening

| | All (N = 375) n (%) | COVIVAC | | AstraZeneca (N = 125) n (%) |
|---|---|---|---|---|
| | | 3 µg (N = 125) n (%) | 6 µg (N = 125) n (%) | |
| **Systolic blood pressure (mmHg)** | | | | |
| > Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| ≤ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Diastolic blood pressure (mmHg)** | | | | |
| > Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| ≤ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Pulse rate (beats /min.)** | | | | |
| > Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| ≤ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Respiratory rate (breaths/min.)** | | | | |
| > Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| ≤ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Temperature (ºC)** | | | | |
| > Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| ≤ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

## Table 23: Physical Examination at Screening

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **General Appearance, n (%)** | | | | |
| Normal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Abnormal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Clinically sig** | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Not done | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **HEENT, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Cardiovascular, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Respiratory, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Abdomen, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Musculoskeletal, n** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Extremity/Skin, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Neurological, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Lymph Nodes, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |

## Table 23: Physical Examination at Screening (continued)

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Not done | | | | |
| Other, n (%) | | | | |
| ….. | | | | |

**Note**: "xx" represent the value number.
** Abnormal result clinically significant

## Table 24: Hematology Test at Screening

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Hemoglobin (g/dL)** | | | | |
| n | xxx | xxx | xxx | xxx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| ≥ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| < Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **White Blood Cell (WBC) (x $10^3$/µL)** | | | | |
| n | xxx | xxx | xxx | xxx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| ≥ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| < Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Platelets (x $10^3$/µL)** | | | | |
| n | xxx | xxx | xxx | xxx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| ≥ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| < Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

## Table 25: Abnormality of Hematology Test with Clinically Significant Result at Screening

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Hemoglobin (g/dL) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| White Blood Cell (WBC) (x $10^3$/µL) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Platelets (x $10^3$/µL) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |

**Note:** "xx" represent the value number.
Only subjects with abnormality of hematology result will be considered in this table.

## Table 26: Chemistry Test at Screening

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Creatinine (mg/dL)** | | | | |
| n | xxx | xxx | xxx | xxx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| ≥ Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| < Grade 2 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **ALT (U/L)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| ≥ Grade 2 | | | | |
| < Grade 2 | | | | |
| **AST (U/L)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| ≥ Grade 2 | | | | |
| < Grade 2 | | | | |
| **Total bilirubin (mg/dL)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| ≥ Grade 2 | | | | |
| < Grade 2 | | | | |

**Note:** "xx" represent the value number.
Only subjects with abnormality of hematology result will be considered in this table.

### Table 27: Abnormality of Chemistry Test with Clinically Significant Result at Screening

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Creatinine (mg/dL) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| ALT (U/L) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| AST (U/L) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Total bilirubin (mg/dL) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |

**Note:** "xx" represent the value number.
Only subjects with abnormality of chemistry result will be considered in this table.

### Table 28: Viral Serology Result at Screening

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **HBsAg** | | | | |
| Positive | | | | |
| Negative | | | | |
| Not done | | | | |
| N/A | | | | |
| **HCV Ab** | | | | |
| Positive | | | | |
| Negative | | | | |
| Not done | | | | |
| N/A | | | | |

**Note:** "xx" represent the value number.

# Appendix 1.B. Reactogenicity - Any Reactions

## Table 29: Any Reactions after Vaccination in Safety Analysis Population

| | COVIVAC | | | |
|---|---|---|---|---|
| | **All (N = 375)** n (%) (95% CI*) | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Total Solicited Reactions – After Any Dose** | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **Severity** | | | | |
| Mild | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Moderate | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Severe | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Potentially life-threatening | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| **Outcome** | | | | |
| Recovered/resolved | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Ongoing at the end of the study | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 29-1: Any Reactions by Age Groups after Vaccination in Safety Analysis Population by Age Groups**

| | COVIVAC | | | |
|---|---|---|---|---|
| | **All (N = 375)** n (%) (95% CI*) | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Total Solicited Reactions – After Any Dose** | | | | |
| 18-59 yrs | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| ≥ 60 yrs | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **Severity** | | | | |
| **18-59 yrs** | | | | |
| Mild | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Moderate | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Severe | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Potentially life-threatening | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| **≥ 60 yrs** | | | | |
| Mild | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Moderate | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Severe | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Potentially life-threatening | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| **Outcomes** | | | | |
| **18-59 yrs** | | | | |
| Recovered/resolved | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Ongoing at the end of the study | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| **≥ 60 yrs** | | | | |
| Recovered/resolved | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |
| Ongoing at the end of the study | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** | xx (xx.x%) **(xx.x-xx.x)** |

# Appendix 1.C. Reactogenicity - Local Reactions

## Table 30: Local Reaction at 30 minutes after Vaccination in Safety Analysis Population

| Reaction | Age | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Local reactions** | Ovarall | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | 18-59 yrs | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | ≥ 60 yrs | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method
Comparing COVIVAC vaccine to active comparator (AstraZeneca); P-value based on Chi-square test.

**Table 31: Local Reaction by Severity within 30 minutes after Vaccination in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Swelling OR Induration** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 31: Local Reaction by Severity within 30 minutes after Vaccination in Safety Analysis Population (continued)**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Swelling OR Induration** | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Erythema** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 31-1: Local Reaction by Severity within 30 minutes in Age 18-59 Years after Vaccination in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Swelling OR Induration** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 31-1: Local Reaction by Severity within 30 minutes in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Swelling OR Induration** | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Erythema** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 31-2: Local Reaction by Severity within 30 minutes in Age ≥ 60 Years after Vaccination in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Swelling OR Induration** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 31-2: Local Reaction by Severity within 30 minutes in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Swelling OR Induration** | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Erythema** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 32: Local Reaction Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= | | x.xxx | x.xxx | |
| | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= | | x.xxx | x.xxx | |
| **Swelling OR Induration** | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= | | x.xxx | x.xxx | |
| | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= | | x.xxx | x.xxx | |
| **Erythema** | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= | | x.xxx | x.xxx | |
| | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= | | x.xxx | x.xxx | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method
Comparing COVIVAC vaccine to active comparator (AstraZeneca); P-value based on Chi-square test.

**Table 32-1: Local Reaction Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population by Age Groups**

| Reaction | Age | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | 18-59 yrs | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | ≥ 60 yrs | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| **Swelling OR Induration** | 18-59 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| | ≥ 60 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| **Erythema** | 18-59 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| | ≥ 60 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method
Comparing COVIVAC vaccine to active comparator (AstraZeneca); P-value based on Chi-square test.

**Table 33: Local Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 33: Local Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Swelling OR Induration** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 33: Local Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Erythema** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 33-1: Local Reaction by Severity Started During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Swelling OR Induration** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 33-1: Local Reaction by Severity Started During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Swelling OR Induration** | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Erythema** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 33-2: Local Reaction by Severity Started During Day 1 - Day 7 in Age ≥ 60 Years after Vaccination in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Swelling OR Induration** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 33-2: Local Reaction by Severity Started During Day 1 - Day 7 in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Swelling OR Induration** | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **Erythema** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 33-3: Local Reaction of Severity ≥ Grade 2 or Higher 7 Days Between Two Dose Levels of COVIVAC after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) |
| **Pain OR Tenderness** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| **Swelling OR Induration** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| **Erythema** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 33-4: Local Reaction of Severity ≥ Grade 2 or Higher 7 Days Between COVIVAC Low Dose and AstraZeneca after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Pain OR Tenderness** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| **Swelling OR Induration** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| **Erythema** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 33-5: Local Reaction of Severity ≥ Grade 2 or Higher 7 Days Between COVIVAC High Dose and AstraZeneca after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Pain OR Tenderness** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| **Swelling OR Induration** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| **Erythema** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 34: New Onset and Ongoing Local Reaction Reported on each Day During Day 1-Day 7 after Vaccination in Safety Analysis Population**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| **Swelling OR Induration** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 34: New Onset and Ongoing Local Reaction Reported on each Day During Day 1-Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Erythema** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 34-1: New Onset and Ongoing Local Reaction Reported on each Day During Day 1- Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| **Swelling OR Induration** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 34-1: New Onset and Ongoing Local Reaction Reported on each Day During Day 1- Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Erythema** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 34-2: New Onset and Ongoing Local Reaction Reported on each Day During Day 1- Day 7 in Age ≥ 60 Year after Vaccination in Safety Analysis Population**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Pain OR Tenderness** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| **Swelling OR Induration** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 34-2: New Onset and Ongoing Local Reaction Reported on each Day During Day 1- Day 7 in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Erythema** | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

# Appendix 1.D. Reactogenicity - Systemic Reactions

## Table 35: Systemic Reaction within 30 minutes after Vaccination in Safety Analysis Population

| Reaction | Age | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Systemic reactions** | Ovarall | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | 18-59 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| | ≥ 60 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method
Comparing COVIVAC vaccine to active comparator (AstraZeneca); P-value based on Chi-square test.

**Table 36: Systemic Reaction by Severity within 30 minutes after Vaccination in Safety Analysis Population**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Fever (≥ 38 °C)** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36: Systemic Reaction by Severity within 30 minutes after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Headache** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36: Systemic Reaction by Severity within 30 minutes after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Fatigue OR Malaise** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36: Systemic Reaction by Severity within 30 minutes after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC | | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| | | 3 µg (N = 125) n (%) (95% CI*) | 6 µg (N = 125) n (%) (95% CI*) | |
| **Myalgia** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36: Systemic Reaction by Severity within 30 minutes after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Arthralgia** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36: Systemic Reaction by Severity within 30 minutes after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC | | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| | | 3 µg (N = 125) n (%) (95% CI*) | 6 µg (N = 125) n (%) (95% CI*) | |
| **Nausea OR Vomiting** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 36-1: Systemic Reaction by Severity within 30 minutes in Age 18-59 Years after Vaccination in Safety Analysis Population**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Fever (≥ 38 °C)** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36-1: Systemic Reaction by Severity within 30 minutes in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Headache** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36-1: Systemic Reaction by Severity within 30 minutes in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Myalgia** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36-1: Systemic Reaction by Severity within 30 minutes in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Arthralgia** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36-1: Systemic Reaction by Severity within 30 minutes in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Nausea OR Vomiting** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 36-2: Systemic Reaction by Severity within 30 minutes in Age ≥ 60 Years after Vaccination in Safety Analysis Population**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Fever (≥ 38 °C)** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36-2: Systemic Reaction by Severity within 30 minutes in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Headache** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36-2: Systemic Reaction by Severity within 30 minutes in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) n (%) (95% CI*) | COVIVAC 3 µg (N = 125) n (%) (95% CI*) | COVIVAC 6 µg (N = 125) n (%) (95% CI*) | AstraZeneca (N = 125) n (%) (95% CI*) |
|---|---|---|---|---|
| **Myalgia** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36-2: Systemic Reaction by Severity within 30 minutes in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Arthralgia** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Table 36-2: Systemic Reaction by Severity within 30 minutes in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Nausea OR Vomiting** | | | | |
| **1st Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |
| **2nd Dose** | | | | |
| None | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life-threatening | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 37: Systemic Reaction Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population**

| Reaction | | All (N = 375) | COVIVAC 3 µg (N = 125) | COVIVAC 6 µg (N = 125) | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Fever (≥ 38 °C)** | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= | | x.xxx | x.xxx | |
| | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= | | x.xxx | x.xxx | |
| **Headache** | 1st Dose | | | | |
| | p-value= | | | | |
| | 2nd Dose | | | | |
| | p-value= | | | | |
| **Fatigue OR Malaise** | 1st Dose | | | | |
| | p-value= | | | | |
| | 2nd Dose | | | | |
| | p-value= | | | | |
| **Myalgia** | 1st Dose | | | | |
| | p-value= | | | | |
| | 2nd Dose | | | | |
| | p-value= | | | | |
| **Arthralgia** | 1st Dose | | | | |
| | p-value= | | | | |
| | 2nd Dose | | | | |
| | p-value= | | | | |
| **Nausea OR Vomiting** | 1st Dose | | | | |
| | p-value= | | | | |
| | 2nd Dose | | | | |
| | p-value= | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method
Comparing COVIVAC vaccine to active comparator (AstraZeneca);

**Table 37-1: Systemic Reaction Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population by Age Groups**

| Reaction | Age | | All (N = 375) | COVIVAC 3 µg (N = 125) | COVIVAC 6 µg (N = 125) | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Fever (≥ 38 °C)** | 18-59 yrs | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | x.xxx | x.xxx | x.xxx | |
| | ≥ 60 yrs | 1st Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| | | 2nd Dose | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | | p-value= | | x.xxx | x.xxx | |
| **Headache** | 18-59 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| | ≥ 60 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| **Fatigue OR Malaise** | 18-59 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| | ≥ 60 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| **Myalgia** | 18-59 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| | ≥ 60 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| **Arthralgia** | 18-59 yrs | 1st Dose | | | | |
| | | p-value= | | | | |

**Table 37-1: Systemic Reaction Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population by Age Groups (continued)**

| Reaction | Age | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Arthralgia** | 18-59 yrs | 2nd Dose | | | | |
| | | p-value= | | | | |
| | ≥ 60 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| **Nausea OR Vomiting** | 18-59 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |
| | ≥ 60 yrs | 1st Dose | | | | |
| | | p-value= | | | | |
| | | 2nd Dose | | | | |
| | | p-value= | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method
Comparing COVIVAC vaccine to active comparator (AstraZeneca);

**Table 38: Systemic Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Fever (≥ 38 °C)** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38: Systemic Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Headache** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38: Systemic Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Fatigue OR Malaise** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38: Systemic Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Myalgia** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38: Systemic Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Arthralgia** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38: Systemic Reaction by Severity Started During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Nausea or Vomiting** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 38-1: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Fever (≥ 38 °C)** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-1: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Headache** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-1: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Fatigue OR Malaise** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-1: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Myalgia** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-1: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Arthralgia** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-1: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Nausea or Vomiting** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 38-2: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age ≥ 60 Years after Vaccination in Safety Analysis Population**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Fever (≥ 38 °C)** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-2: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Headache** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-2: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age Age ≥60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Fatigue OR Malaise** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-2: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age Age ≥60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Myalgia** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-2: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age Age ≥60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Arthralgia** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Table 38-2: Systemic Reaction by Severity Started During Day 1 - Day 7 in Age Age ≥60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Nausea or Vomiting** | | | | |
| **1st Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **2nd Dose** | | | | |
| None | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Potentially life-threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 38-3: Systemic Reaction of Severity ≥ Grade 2 or Higher 7 Days Between Two Dose Levels of COVIVAC after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) |
| **Fever (≥ 38 °C)** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Headache** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Fatigue OR Malaise** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Table 38-3: Systemic Reaction of Severity ≥ Grade 2 or Higher 7 Days Between Two Dose Levels of COVIVAC after Vaccination in Safety Analysis Population (Continued)**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) |
| **Arthralgia** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Myalgia** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Nausea or Vomiting** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 38-4: Systemic Reaction of Severity ≥ Grade 2 or Higher 7 Days Between COVIVAC Low Dose and AstraZeneca after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Fever (≥ 38 °C)** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Headache** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Fatigue OR Malaise** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Table 38-4: Systemic Reaction of Severity ≥ Grade 2 or Higher 7 Days Between COVIVAC Low Dose and AstraZeneca after Vaccination in Safety Analysis Population (Continued)**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Myalgia** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Arthralgia** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Nausea or Vomiting** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 38-5: Systemic Reaction of Severity ≥ Grade 2 or Higher 7 Days Between COVIVAC Low Dose and High Dose after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) |
| **Fever (≥ 38 °C)** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Headache** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Fatigue OR Malaise** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Table 38-5: Systemic Reaction of Severity ≥ Grade 2 or Higher 7 Days Between COVIVAC Low Dose and High Dose after Vaccination in Safety Analysis Population (Continued)**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) |
| **Myalgia** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Arthralgia** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **Nausea or Vomiting** | | | |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 39: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 after Vaccination in Safety Analysis Population**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Fever (≥ 38 °C) | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Headache | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 39: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Fatigue OR Malaise | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Myalgia | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 39: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Arthralgia | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Nausea or Vomiting | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 39-1: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Fever (≥ 38 °C) | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Headache | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 39-1: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 in Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Fatigue OR Malaise | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Myalgia | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 39-1: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 Age 18-59 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Arthralgia | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Nausea or Vomiting | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 39-2: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 in Age ≥ 60 Years after Vaccination in Safety Analysis Population**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Fever (≥ 38 °C) | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Headache | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 39-2: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Fatigue OR Malaise | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Myalgia | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Table 39-2: New Onset and Ongoing Local Reaction Reported on each Day During Day 1 - Day 7 in Age ≥ 60 Years after Vaccination in Safety Analysis Population (continued)**

| Reaction | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| Arthralgia | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| Nausea or Vomiting | **1st Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |
| | **2nd Dose** | | | | |
| | Day 1 | | | | |
| | Day 2 | | | | |
| | Day 3 | | | | |
| | …….. | | | | |
| | Day 7 | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

# Appendix 1.E. Adverse Events

## Table 40: Overall Number of Subjects with Adverse Events after Any Dose of Vaccination in Safety Analysis Population

| | All (N = 375) (95% CI*) | COVIVAC 3 µg (N = 125) (95% CI*) | COVIVAC 6 µg (N = 125) (95% CI*) | AstraZeneca (N = 125) (95% CI*) |
|---|---|---|---|---|
| **Total Number of Events** | xxx | xxx | xxx | xxx |
| **Total Immediate Adverse Events – After Any Dose** | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **Severity** | | | | |
| Mild | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Moderate | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Severe | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Life threatening | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Death | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **Total Unsolicited Adverse Events within 28 Days of Vaccination – After Any Dose** | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **Relationship to Study Vaccine** | | | | |
| Related | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| Not related | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **Severity** | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Life threatening | | | | |
| Death | | | | |
| **Outcome** | | | | |
| Recovered/resolved without sequelae | | | | |
| Recovered/resolved with sequelae | | | | |
| Ongoing at the end of the study | | | | |
| Death | | | | |
| Unknown. The outcome of the AE is not known | | | | |

**Table 40: Overall Number of Subjects with Adverse Events after each Vaccination in Safety Analysis Population (continued)**

| | All (N = 375) (95% CI*) | COVIVAC 3 µg (N = 125) (95% CI*) | COVIVAC 6 µg (N = 125) (95% CI*) | AstraZeneca (N = 125) (95% CI*) |
|---|---|---|---|---|
| **Total SAEs – After Any Dose** | | | | |
| **Relationship to Study Vaccine** | | | | |
| Related | | | | |
| Not related | | | | |
| **Severity** | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Life threatening | | | | |
| Death | | | | |
| **Outcome** | | | | |
| Ongoing | | | | |
| Unknown/lost to follow up | | | | |
| Recovered/resolved without sequelae | | | | |
| Recovered/resolved with sequelae | | | | |
| Death | | | | |
| **Seriousness criteria** | | | | |
| Death | | | | |
| Life threatening | | | | |
| Inpatient hospitalization/prolongation of existing hospitalization | | | | |
| Persistent or significant disability/incapacity | | | | |
| Congenital anomaly/birth defect | | | | |
| Important medical event | | | | |

**Table 40: Overall Number of Subjects with Adverse Events after each Vaccination in Safety Analysis Population (continued)**

| | All (N = 375) (95% CI*) | COVIVAC 3 µg (N = 125) (95% CI*) | COVIVAC 6 µg (N = 125) (95% CI*) | AstraZeneca (N = 125) (95% CI*) |
|---|---|---|---|---|
| **Total Deaths – After Any Dose** | | | | |
| **Relationship to Study Vaccine** | | | | |
| Related | | | | |
| Not related | | | | |

**Table 41: Overall Number of Subjects with Non-Serious Adverse Events from Combined Solicited and Unsolicited Adverse Events Onset during the First 28 days after each Vaccination in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Overall, n (%)** | | | | |
| with one or more adverse events | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| with no adverse event | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| with vaccine-related adverse events | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| **After 1st Dose Vaccination** | | | | |
| with one or more adverse events | | | | |
| with no adverse event | | | | |
| with vaccine-related adverse events | | | | |
| **After 2nd Dose Vaccination** | | | | |
| with one or more adverse events | | | | |
| with no adverse event | | | | |
| with vaccine-related adverse events | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 41-1: Overall Number of Subjects with Non-Serious Adverse Events from Combined Solicited and Unsolicited Adverse Events Onset during the First 28 days after each Vaccination by Age Groups in Safety Analysis Population**

| | Age | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) | n (%) (95% CI*) |
| **Overall, n (%)** | | | | | |
| with one or more adverse events | 18-59 yrs | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | ≥ 60 yrs | | | | |
| with no adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| **After 1st Dose Vaccination** | | | | | |
| with one or more adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| **After 2nd Dose Vaccination** | | | | | |
| with one or more adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |

**Note**: *Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 42: Summary of Non-Serious Adverse Events from Combined Solicited and Unsolicited Adverse Events Onset during the First 28 days after each Vaccination by MedDRA term in Safety Analysis Population**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** All SOC | All PT | xx | xx (xx.x %) | xx | xx (xx.x %) | xx | xx (xx.x %) | xx | xx (xx.x %) |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **1st Dose** All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **2nd Dose** All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
"NE" is number of events.
"n" is number of subject who has at least one adverse event.

**Table 42-1: Summary of Non-Serious Adverse Events from Combined Solicited and Unsolicited Adverse Events Onset during the First 28 days after each Vaccination by MedDRA term in Age 18-59 Years in Safety Analysis Population**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** All SOC | All PT | xx | xx (xx.x %) | xx | xx (xx.x %) | xx | xx (xx.x %) | xx | xx (xx.x %) |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **1st Dose** All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **2nd Dose** All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
"NE" is number of events.
"n" is number of subject who has at least one adverse event.

**Table 42-2: Summary of Non-Serious Adverse Events from Combined Solicited and Unsolicited Adverse Events Onset during the First 28 days after each Vaccination by MedDRA term in Age ≥ 60 Years in Safety Analysis Population**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** All SOC | All PT | xx | xx (xx.x %) | xx | xx (xx.x %) | xx | xx (xx.x %) | xx | xx (xx.x %) |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **1st Dose** All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **2nd Dose** All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
"NE" is number of events.
"n" is number of subject who has at least one adverse event.

**Table 43: Overall Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI) | n (%) (95% CI) | n (%) (95% CI) | n (%) (95% CI) |
| **Overall Adverse event, n (%)** | | | | |
| with one or more adverse events | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| with no adverse event | | | | |
| with vaccine-related adverse events | | | | |
| withdrawn due to an adverse event | | | | |
| **Adverse event, n (%)** | | | | |
| **1st Dose Vaccination** | | | | |
| with one or more adverse events | | | | |
| with no adverse event | | | | |
| with vaccine-related adverse events | | | | |
| withdrawn due to an adverse event | | | | |
| **2nd Dose Vaccination** | | | | |
| with one or more adverse events | | | | |
| with no adverse event | | | | |
| with vaccine-related adverse events | | | | |
| withdrawn due to an adverse event | | | | |
| **Serious adverse event, n (%)** | | | | |
| **1st Dose Vaccination** | | | | |
| with one or more serious adverse events | | | | |
| with no serious adverse event | | | | |
| with vaccine-related serious adverse events | | | | |
| withdrawn due to a serious adverse event | | | | |
| SAEs leading to death | | | | |
| **2nd Dose Vaccination** | | | | |
| with one or more serious adverse events | | | | |
| with no serious adverse event | | | | |
| with vaccine-related serious adverse events | | | | |
| withdrawn due to a serious adverse event | | | | |
| SAEs leading to death | | | | |

**Table 43: Overall Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination in Safety Analysis Population (continued)**

| | All (N = 375) n (%) (95% CI) | COVIVAC 3 µg (N = 125) n (%) (95% CI) | COVIVAC 6 µg (N = 125) n (%) (95% CI) | AstraZeneca (N = 125) n (%) (95% CI) |
|---|---|---|---|---|
| **Medically-attended AEs, n (%)** | | | | |
| **1st Dose Vaccination** | | | | |
| with one or more MAAEs | | | | |
| with no MAAE | | | | |
| with vaccine-related MAAEs | | | | |
| withdrawn due to an MAAE | | | | |
| **2nd Dose Vaccination** | | | | |
| with one or more MAAEs | | | | |
| with no MAAE | | | | |
| with vaccine-related MAAEs | | | | |
| withdrawn due to an MAAE | | | | |
| **AEs of special interest, n (%)** | | | | |
| **1st Dose Vaccination** | | | | |
| with one or more AESIs | | | | |
| potential immune-mediated medical conditions (PIMMC) | | | | |
| potentially related to COVID-19 | | | | |
| with no AESI | | | | |
| with vaccine-related AESIs | | | | |
| withdrawn due to an AESI | | | | |
| **2nd Dose Vaccination** | | | | |
| with one or more AESIs | | | | |
| potential immune-mediated medical conditions (PIMMC) | | | | |
| potentially related to COVID-19 | | | | |
| with no AESI | | | | |
| with vaccine-related AESIs | | | | |
| withdrawn due to an AESI | | | | |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
*Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 43-1: Number of Subjects with Adverse Events Onset during the First 28 Days After Each Vaccination by Age Groups in Safety Analysis Population**

| | Age | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI) | n (%) (95% CI) | n (%) (95% CI) | n (%) (95% CI) |
| **Overall Adverse event, n (%)** | | | | | |
| with one or more adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to an adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| **Adverse event, n (%)** | | | | | |
| **1st Dose Vaccination** | | | | | |
| with one or more adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to an adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| **2nd Dose Vaccination** | | | | | |
| with one or more adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to an adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| **Serious adverse event, n (%)** | | | | | |
| **1st Dose Vaccination** | | | | | |
| with one or more serious adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no serious adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related serious adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to a serious adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| SAEs leading to death | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |

**Table 43-1: Number of Subjects with Adverse Events Onset during the First 28 Days After Each Vaccination by Age Groups in Safety Analysis Population (continued)**

| | Age | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI) | n (%) (95% CI) | n (%) (95% CI) | n (%) (95% CI) |
| **Serious adverse event, n (%)** | | | | | |
| **2nd Dose Vaccination** | | | | | |
| with one or more serious adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no serious adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related serious adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to a serious adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| SAEs leading to death | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| **Medically-attended AEs, n (%)** | | | | | |
| **1st Dose Vaccination** | | | | | |
| with one or more MAAEs | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no MAAE | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related MAAEs | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to an MAAE | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| **2nd Dose Vaccination** | | | | | |
| with one or more MAAEs | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no MAAE | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related MAAEs | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to an MAAE | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |

**Table 43-1: Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination in Age Groups in Safety Analysis Population (continued)**

| | Age | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI) | n (%) (95% CI) | n (%) (95% CI) | n (%) (95% CI) |
| **AEs of special interest, n (%)** | | | | | |
| **1st Dose Vaccination** | | | | | |
| with one or more AESIs | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| potential immune-mediated medical conditions (PIMMC) | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| potentially related to COVID-19 | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no AESI | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related AESIs | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to an AESI | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| **2nd Dose Vaccination** | | | | | |
| with one or more AESIs | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| potential immune-mediated medical conditions (PIMMC) | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| potentially related to COVID-19 | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with no AESI | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related AESIs | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to an AESI | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
*Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 43-2: Number of Subjects with Adverse Events with Severity ≥ Grade 2 or Higher 28 Days of Adverse Events Grade 2 Between Two Dose Levels of COVIVAC after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Table 43-3: Number of Subjects with Adverse Events with Severity ≥ Grade 2 or Higher 28 Days of Adverse Events Grade 2 Between COVIVAC Low Dose and AstraZeneca after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Table 43-4: Number of Subjects with Adverse Events with Severity ≥ Grade 2 or Higher 28 Days of Adverse Events Grade 2 Between COVIVAC High Dose and AstraZeneca after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Table 44: Overall Number of Subjects with Serious Adverse Events throughout the Entire Study Period in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | n (%) (95% CI) * | n (%) (95% CI) * | n (%) (95% CI) * | n (%) (95% CI) * |
| with one or more serious adverse | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| with no serious adverse event | | | | |
| with vaccine-related serious adverse events | | | | |
| with medically-attended serious AE (MAAEs) | | | | |
| with serious adverse events of special interest (AESI) | | | | |
| potential immune-mediated medical conditions (PIMMC) | | | | |
| potentially related to COVID-19 | | | | |
| withdrawn due to a serious adverse event | | | | |
| SAEs leading to death | | | | |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
*Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 44-1: Overall Number of Subjects with Serious Adverse Events throughout the Entire Study Period by Age Groups in Safety Analysis Population**

| | Age | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| | | n (%) (95% CI) * | n (%) (95% CI) * | n (%) (95% CI) * | n (%) (95% CI) * |
| with one or more serious adverse events | 18-59 yrs | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | ≥ 60 yrs | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| with no serious adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with vaccine-related serious adverse events | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with medically-attended serious AE (MAAEs) | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| with serious adverse events of special interest (AESI) | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| potential immune-mediated medical conditions (PIMMC) | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| potentially related to COVID-19 | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| withdrawn due to a serious adverse event | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |
| SAEs leading to death | 18-59 yrs | | | | |
| | ≥ 60 yrs | | | | |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
*Two-sided 95% CIs computed via the Clopper-Pearson method

**Table 44-2: Number of Subjects with Serious Adverse Events Throughout Study Between Two Dose Levels of COVIVAC after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **6 µg (N = 125)** n (%) (95% CI*) |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Table 44-3: Number of Subjects with Serious Adverse Events Throughout Study Between COVIVAC Low Dose and AstraZeneca after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Table 44-4: Number of Subjects with Serious Adverse Events Throughout Study Between COVIVAC High Dose and AstraZeneca after Vaccination in Safety Analysis Population**

| | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** n (%) (95% CI*) | **AstraZeneca (N = 125)** n (%) (95% CI*) |
| **Any dose** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value= ….. | | |

**Table 45: Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination by Severity in Safety Analysis Population**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **1st Dose Vaccination** | | | | |
| with one or more adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
***** Maximum severity grade will be considered.

**Table 45: Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination by Severity in Safety Analysis Population (continued)**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **2nd Dose Vaccination** | | | | |
| with one or more adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
***** Maximum severity grade will be considered.

**Table 45-1: Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination by Severity in Age 18-59 years**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **1st Dose Vaccination** | | | | |
| with one or more adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
***** Maximum severity grade will be considered.

**Table 45-1: Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination by Severity in Age 18-59 Years (continued)**

| | All (N = 375) | COVIVAC 3 µg (N = 125) | COVIVAC 6 µg (N = 125) | AstraZeneca (N = 125) |
|---|---|---|---|---|
| **2nd Dose Vaccination** | | | | |
| with one or more adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
***** Maximum severity grade will be considered.

**Table 45-2: Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination by Severity in Age ≥ 60 years**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **1st Dose Vaccination** | | | | |
| with one or more adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Table 45-2: Number of Subjects with Adverse Events Onset during the First 28 days after each Vaccination by Severity in Age ≥ 60 Years (continued)**

| | All (N = 375) | COVIVAC 3 µg (N = 125) | COVIVAC 6 µg (N = 125) | AstraZeneca (N = 125) |
|---|---|---|---|---|
| **2nd Dose Vaccination** | | | | |
| with one or more adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.
***** Maximum severity grade will be considered.

**Table 46: Number of Subjects with Serious Adverse Events by Severity throughout the Study Period**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more serious adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no serious adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related serious adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 46-1: Number of Subjects with Serious Adverse Events by Severity throughout the Study Period in Age 18-59 Years**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more serious adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no serious adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related serious adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 46-2: Number of Subjects with Serious Adverse Events by Severity throughout the Study Period in Age ≥ 60 Years**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more serious adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no serious adverse event | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related serious adverse events by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 47: Number of Subjects with Medically-Attended AEs (MAAEs) by Severity throughout the Study Period**

| | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more MAAEs by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no MAAE | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related MAAEs by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | | |
| **System Organ Class Term** | **Preferred Term** | | | | |
| …… | …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 47-1: Number of Subjects with Medically-Attended AEs (MAAEs) by Severity throughout the Study Period in Age 18-59 Years**

| | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more MAAEs by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no MAAE | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related MAAEs by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | | |
| **System Organ Class Term** | **Preferred Term** | | | | |
| …… | …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 47-2: Number of Subjects with Medically-Attended AEs (MAAEs) by Severity throughout the Study Period in Age ≥ 60 Years**

| | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more MAAEs by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no MAAE | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related MAAEs by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | | |
| **System Organ Class Term** | **Preferred Term** | | | | |
| …… | …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 48: Number of Subjects with Adverse Events of Special Interest (AESI) by Severity throughout the Study Period**

| | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AESI by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AESI | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AESI by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | | |
| **System Organ Class Term** | **Preferred Term** | | | | |
| …… | …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 48-1: Number of Subjects with Adverse Events of Special Interest (AESI) by Severity throughout the Study Period in Age 18-59 Years**

| | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AESI by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AESI | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AESI by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | | |
| **System Organ Class Term** | **Preferred Term** | | | | |
| …… | …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 48-2: Number of Subjects with Adverse Events of Special Interest (AESI) by Severity throughout the Study Period in Age ≥ 60 Years**

| | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AESI by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AESI | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AESI by severity* | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | | |
| **System Organ Class Term** | **Preferred Term** | | | | |
| …… | …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 49: Number of Subjects with Adverse Events of Special Interest (AESI) Relevant to COVID-19 by Severity throughout the Study Period**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AESIs relevant to COVID-19 by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AESI relevant to COVID-19 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AESI by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number

***** Maximum severity grade will be considered.

**Table 49-1: Number of Subjects with Adverse Events of Special Interest (AESI) Relevant to COVID-19 by Severity throughout the Study Period in Age 18 -59 Years**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AESIs relevant to COVID-19 by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AESI relevant to COVID-19 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AESI by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number

***** Maximum severity grade will be considered.

**Table 49-2: Number of Subjects with Adverse Events of Special Interest (AESI) Relevant to COVID-19 by Severity throughout the Study Period in Age ≥ 60 Years**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AESIs relevant to COVID-19 by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AESI relevant to COVID-19 | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AESI by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number

***** Maximum severity grade will be considered.

**Table 50: Number of Subjects with Adverse Events of Potential Immune-Mediated Medical Conditions (PIMMC) by Severity throughout the Study Period**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AEs of PIMMC by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AE of PIMMC | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AEs of PIMMC by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 50-1: Number of Subjects with Adverse Events of Potential Immune-Mediated Medical Conditions (PIMMC) by Severity throughout the Study Period in Age 18-59 Years**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AEs of PIMMC by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AE of PIMMC | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AEs of PIMMC by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 50-2: Number of Subjects with Adverse Events of Potential Immune-Mediated Medical Conditions (PIMMC) by Severity throughout the Study Period in Age ≥ 60 Years**

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| with one or more AEs of PIMMC by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no AE of PIMMC | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with vaccine-related AEs of PIMMC by severity* | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade1 (Mild) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade2 (Moderate) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade3 (Severe) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Grade4 (Potentially life-threatening) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Subjects with specific adverse events** | | | | |
| **System Organ Class Term** **Preferred Term** | | | | |
| …… …… | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx xx.x%) |

**Note**: "N" is the total number of subject in each group and "xx" represent the value number.

***** Maximum severity grade will be considered.

**Table 51: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| AE During the first 28 days post –first vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| AE During the first 28 days post –second vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| SAE During the first 28 days post –first vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| SAE During the first 28 days post –second vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| MAAE During the first 28 days post –first injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| MAAE During the first 28 days post –second injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| AESI During the first 28 days post –first injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| AESI During the first 28 days post –second injection (Visit 6 (Day 57)) | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51-1: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade in Age 18-59 Years**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| AE During the first 28 days post –first vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| AE During the first 28 days post –second vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51-1: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade in Age 18-59 Years (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| SAE During the first 28 days post –first vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| SAE During the first 28 days post –second vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51-1: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade in Age 18-59 Years (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| MAAE During the first 28 days post –first injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| MAAE During the first 28 days post –second injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51-1: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade in Age 18-59 Years (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| AESI During the first 28 days post –first injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| AESI During the first 28 days post –second injection (Visit 6 (Day 57)) | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51-2: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade in Age ≥ 60 Years**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| AE During the first 28 days post –first vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| AE During the first 28 days post –second vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51-2: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade in Age ≥ 60 Years (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| SAE During the first 28 days post –first vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| SAE During the first 28 days post –second vaccination | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51-2: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade in Age ≥ 60 Years (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| MAAE During the first 28 days post –first injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| MAAE During the first 28 days post –second injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 51-2: Duration Days of Adverse Event During First 28 Days Post Vaccination by Severity Grade in Age ≥ 60 Years (continued)**

| | Severity | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| AESI During the first 28 days post –first injection | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| AESI During the first 28 days post –second injection (Visit 6 (Day 57)) | All, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |
| | Related, Mean of days (SD) | | | | |
| | Mild | | | | |
| | Moderate | | | | |
| | Severe | | | | |
| | Potentially life-threatening | | | | |

**Table 52: Summary of Adverse Events during the First 28 days after each Vaccination by MedDRA term**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **1st dose** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **2nd dose** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of patient in each group and "xx" represent the value number.
"NE" is number of events.; "n" is number of subject who has at least one adverse event.

**Table 52-1: Summary of Adverse Events during the First 28 days after each Vaccination by MedDRA term in Age 18-59 Years**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **1st dose** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **2nd dose** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of patient in each group and "xx" represent the value number.
"NE" is number of events.; "n" is number of subject who has at least one adverse event.

**Table 52-2: Summary of Adverse Events during the First 28 days after each Vaccination by MedDRA term in Age ≥ 60 Years**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **1st dose** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| **2nd dose** | | | | | | | | | |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of patient in each group and "xx" represent the value number.
"NE" is number of events.; "n" is number of subject who has at least one adverse event.

**Table 53: Summary of Serious Adverse Events throughout the Entire Study Period by MedDRA term**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of patient in each group and "xx" represent the value number.
"NE" is number of events.
"n" is number of subject who has at least one adverse event.

**Table 53-1: Summary of Serious Adverse Events throughout the Entire Study Period by MedDRA term in Age 18-59 Years**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of patient in each group and "xx" represent the value number.
"NE" is number of events.
"n" is number of subject who has at least one adverse event.

**Table 53-2: Summary of Serious Adverse Events throughout the Entire Study Period by MedDRA term in Age ≥ 60 Years**

| System Organ Class (SOC) | Preferred Term (PT) | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| All SOC | All PT | | | | | | | | |
| SOC 1 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |
| SOC 2 | All | | | | | | | | |
| | PT 1 | | | | | | | | |
| | PT 2 | | | | | | | | |

**Note**: "N" is the total number of patient in each group and "xx" represent the value number.
"NE" is number of events.
"n" is number of subject who has at least one adverse event.

**Table 54: Summary of Serious Adverse Event during the First 28 days after each Vaccination by Criteria**

| Criteria | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |
| **1st dose** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |
| **2nd dose** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 54-1: Summary of Serious Adverse Event during the First 28 days after each Vaccination by Criteria in Age 18-59 Years**

| Criteria | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |
| **1st dose** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |
| **2nd dose** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |

**Table 54-1: Summary of Serious Adverse Event during the First 28 days after each Vaccination by Criteria in Age 18-59 Years (continued)**

| Criteria | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| Is medically significant | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 54-2: Summary of Serious Adverse Event during the First 28 days after each Vaccination by Criteria n Age ≥ 60 Years**

| Criteria | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |
| **1st dose** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |
| **2nd dose** | | | | | | | | |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |

**Table 54-2: Summary of Serious Adverse Event during the First 28 days after each Vaccination by Criteria in Age ≥ 60 Years (continued)**

| Criteria | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| Is medically significant | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 55: Summary of Serious Adverse Event throughout the Study Period by Criteria**

| Criteria | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 55-1: Summary of Serious Adverse Event throughout the Study Period by Criteria in Age 18-59 Years**

| Criteria | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 55-2: Summary of Serious Adverse Event throughout the Study Period by Criteria in Age ≥ 60 Years**

| Criteria | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| All | | | | | | | | |
| Results in death | | | | | | | | |
| Is life-threatening | | | | | | | | |
| Requires inpatient hospitalization or prolongation of an existing hospitalization | | | | | | | | |
| Results in persistent or significant disability or incapacity | | | | | | | | |
| Results in a congenital anomaly or birth defect | | | | | | | | |
| Is medically significant | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 56: Summary of Adverse Event by Outcome during the First 28 Days after each Vaccination**

| Outcome | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 56-1: Summary of Adverse Event by Outcome during the First 28 Days after each Vaccination in Age 18-59 Years**

| Outcome | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 56-2: Summary of Adverse Event by Outcome during the First 28 Days after each Vaccination in Age ≥ 60 Years**

| Outcome | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 57: Summary of Serious Adverse Event by Outcome throughout the Study Period**

| Outcome | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |
| **Age 18-59 years** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |
| **Age ≥ 60 years** | | | | | | | | |
| All | | | | | | | | |
| Ongoing | | | | | | | | |
| Recovered/Resolved | | | | | | | | |
| Recovered/Resolved with sequelae | | | | | | | | |
| Fatal | | | | | | | | |
| Unknown | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 58: Summary of Adverse Event during the First 28 Days after each Vaccination by Relationship to Study Vaccine**

| Relationship to Study Vaccine | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 58-1: Summary of Adverse Event during the First 28 Days after each Vaccination by Relationship to Study Vaccine in Age 18-59 Years**

| Relationship to Study Vaccine | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 58-2: Summary of Adverse Event during the First 28 Days after each Vaccination by Relationship to Study Vaccine in Age ≥ 60 Years**

| Relationship to Study Vaccine | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 59: Summary of Serious Adverse Event throughout the Study Period by Relationship to Study Vaccine**

| Relationship to Study Vaccine | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |
| **Age 18-59 Years** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |
| **Age ≥ 60 Years** | | | | | | | | |
| All | | | | | | | | |
| Related | | | | | | | | |
| Not related | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 60: Summary of Adverse event by Action Taken to the Study Vaccine during the First 28 Days after each Vaccination**

| Action Taken to the Study Vaccine | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |

**Note**: NE – Number of events
n (%) – Number of subject and percentage

**Table 60-1: Summary of Adverse event by Action Taken to the Study Vaccine during the First 28 Days after each Vaccination in Age 18-59 Years**

| Action Taken to the Study Vaccine | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |

**Table 60-2: Summary of Adverse event by Action Taken to the Study Vaccine during the First 28 Days after each Vaccination in Age ≥ 60 Years**

| Action Taken to the Study Vaccine | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |
| **1st Dose** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |
| **2nd Dose** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |

**Table 61: Summary of Serious Adverse Event by Action Taken to the Study Vaccine throughout the Study Period**

| Action Taken to the Study Vaccine | All (N = 375) | | COVIVAC | | | | AstraZeneca (N = 125) | |
|---|---|---|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | | 6 µg (N = 125) | | | |
| | NE | n (%) | NE | n (%) | NE | n (%) | NE | n (%) |
| **Overall** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |
| **Age 18-59 Years** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |
| **Age ≥ 60 Years** | | | | | | | | |
| All | | | | | | | | |
| Withdrawn | | | | | | | | |
| Delayed | | | | | | | | |
| Continued | | | | | | | | |
| Not applicable | | | | | | | | |

**Note**: NE: Number of events
n: Number of subject with at least one AE / %: (n/N)*100

# Appendix 1.F. Vital Signs

## Table 62: Overall Number of Subject with Abnormal of Vital Sign result at Post -First Vaccination

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Overall, n (%)** | | | | |
| Systolic Blood Pressure (mmHg) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Diastolic Blood Pressure (mmHg) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Pulse (Beats/min) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Respiratory Rate (Breaths/min) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Temperature (°C) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with one or more abnormal result | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no abnormal result | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Post-first vaccination** | | | | |
| Systolic Blood Pressure (mmHg) | | | | |
| Diastolic Blood Pressure (mmHg) | | | | |
| Pulse (Beats/min) | | | | |
| Respiratory Rate (Breaths/min) | | | | |
| Temperature (°C) | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |
| **Visit 2 (Day 8)** | | | | |
| Systolic Blood Pressure (mmHg) | | | | |
| Diastolic Blood Pressure (mmHg) | | | | |
| Pulse (Beats/min) | | | | |
| Respiratory Rate (Breaths/min) | | | | |
| Temperature (°C) | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |

## Table 63: Overall Number of Subject with Abnormal of Vital Sign at Post- Second Vaccination

| | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Overall, n (%)** | | | | |
| Systolic Blood Pressure (mmHg) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Diastolic Blood Pressure (mmHg) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Pulse (Beats/min) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Respiratory Rate (Breaths/min) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Temperature (°C) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with one or more abnormal result | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no abnormal result | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Post-second vaccination** | | | | |
| Systolic Blood Pressure (mmHg) | | | | |
| Diastolic Blood Pressure (mmHg) | | | | |
| Pulse (Beats/min) | | | | |
| Respiratory Rate (Breaths/min) | | | | |
| Temperature (°C) | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |
| **Visit 4 (Day 36)** | | | | |
| Systolic Blood Pressure (mmHg) | | | | |
| Diastolic Blood Pressure (mmHg) | | | | |
| Pulse (Beats/min) | | | | |
| Respiratory Rate (Breaths/min) | | | | |
| Temperature (°C) | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |
| **Visit 5 (Day 43)** | | | | |
| Systolic Blood Pressure (mmHg) | | | | |
| Diastolic Blood Pressure (mmHg) | | | | |
| Pulse (Beats/min) | | | | |
| Respiratory Rate (Breaths/min) | | | | |
| Temperature (°C) | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |
| **Visit 6 (Day 57)** | | | | |
| Systolic Blood Pressure (mmHg) | | | | |
| Diastolic Blood Pressure (mmHg) | | | | |
| Pulse (Beats/min) | | | | |
| Respiratory Rate (Breaths/min) | | | | |
| Temperature (°C) | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |
| **Visit 7 (Day 197)** | | | | |
| Systolic Blood Pressure (mmHg) | | | | |
| Diastolic Blood Pressure (mmHg) | | | | |
| Pulse (Beats/min) | | | | |
| Respiratory Rate (Breaths/min) | | | | |
| Temperature (°C) | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |

## Table 64 Systolic Blood Pressure (mmHg) Post-first Vaccination Compared to Pre-first Vaccination

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 2 (Day 8)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 8 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Note:** * P-value based on Kruskal Wallis Test
"xx" represent the value number.

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Hypertension (systolic) – mm Hg | 141 – 150 | 151 – 165 | > 165 | ER visit or hospitalization for malignant hypertension |
| Hypotension (systolic) – mm Hg | 85 – 89 | 80 – 84 | < 80 | ER visit or hospitalization for hypotensive shock |

**Table 65: Systolic Blood Pressure (mmHg) Post–second Vaccination Compared to Pre–second Vaccination**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 4 (Day 36)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 36 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Table 65: Systolic Blood Pressure (mmHg) Post–second Vaccination Compared to Pre–second Vaccination (continued)**

| | All (N=375) | COVIVAC 3 µg (N = 125) | COVIVAC 6 µg (N = 125) | AstraZeneca (N = 125) |
|---|---|---|---|---|
| **Visit 5 (Day 43)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 43 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 6 (Day 57)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 57 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 7 (Day 197)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 197 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

## Table 65: Systolic Blood Pressure (mmHg) Post–second Vaccination Compared to Pre–second Vaccination (continued)

**Note:** * P-value based on Kruskal Wallis Test
"xx" represent the value number.

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Hypertension (systolic) – mm Hg | 141 – 150 | 151 – 165 | > 165 | ER visit or hospitalization for malignant hypertension |
| Hypotension (systolic) – mm Hg | 85 – 89 | 80 – 84 | < 80 | ER visit or hospitalization for hypotensive shock |

## Table 66: Diastolic Blood Pressure (mmHg) Post-first Vaccination Compared to Pre-first Vaccination

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 2 (Day 8)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 8 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Note:** * P-value based on Kruskal Wallis Test
"xx" represent the value number.

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Hypertension (diastolic) – mm Hg | 91 – 99 | 100 – 105 | > 105 | ER visit or hospitalization for malignant hypertension |

**Table 67: Diastolic Blood Pressure (mmHg) Post–second Vaccination Compared to Pre–second Vaccination**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 4 (Day 36)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 36 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Table 67: Diastolic Blood Pressure (mmHg) Post–second Vaccination Compared to Pre–second Vaccination (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Visit 5 (Day 43)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 43 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 6 (Day 57)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 57 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 7 (Day 197)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 197 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

## Table 67: Diastolic Blood Pressure (mmHg) Post–second Vaccination Compared to Pre–second Vaccination (continued)

**Note:** * P-value based on Kruskal Wallis Test
"xx" represent the value number.

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Hypertension (diastolic) – mm Hg | 91 – 99 | 100 – 105 | > 105 | ER visit or hospitalization for malignant hypertension |

## Table 68: Pulse (Beats/min) Post-first Vaccination Compared to Pre-first Vaccination

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 2 (Day 8)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 8 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Note:** * P-value based on Kruskal Wallis Test

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Tachycardia – beats per minute | 101 – 115 | 116 – 130 | > 130 | Hospitalization for arrhythmia |
| Bradycardia – beats per minute [b] | 50 – 54 | 45 – 49 | < 45 | ER visit or hospitalization for arrhythmia |

[b] Grade 1 bradycardia or grade 1 tachypnea will not be considered an abnormality for this study, unless judged to be clinically significant by the PI.

## Table 69: Pulse (Beats/min) Post–second Vaccination Compared to Pre–second Vaccination

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post- second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 4 (Day 36)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 36 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Table 69: Pulse (Beats/min) Post–second Vaccination Compared to Pre–second Vaccination (continued)**

| | All (N=375) | COVIVAC 3 µg (N = 125) | COVIVAC 6 µg (N = 125) | AstraZeneca (N = 125) |
|---|---|---|---|---|
| **Visit 5 (Day 43)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 43 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 6 (Day 57)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 57 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 7 (Day 197)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 197 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

## Table 69: Pulse (Beats/min) Post–second Vaccination Compared to Pre–second Vaccination (continued)

**Note:** * P-value based on Kruskal Wallis Test

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Tachycardia – beats per minute | 101 – 115 | 116 – 130 | > 130 | Hospitalization for arrhythmia |
| Bradycardia – beats per minute [a] | 50 – 54 | 45 – 49 | < 45 | ER visit or hospitalization for arrhythmia |

[a] Grade 1 bradycardia or grade 1 tachypnea will not be considered an abnormality for this study, unless judged to be clinically significant by the PI.

## Table 70: Respiratory Rate (Breaths/min) Post-first Vaccination Compared to Pre-first Vaccination

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 2 (Day 8)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 8 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Note:** * P-value based on Kruskal Wallis Test

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Respiratory Rate – breaths per minute | 21 – 23 | 24 – 27 | > 27 | Intubation |

**Table 71: Respiratory Rate (Breaths/min) Post–second Vaccination Compared to Pre–second Vaccination**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 4 (Day 36)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 36 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Table 71: Respiratory Rate (Breaths/min) Post–second Vaccination Compared to Pre–second Vaccination (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Visit 5 (Day 43)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 43 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 6 (Day 57)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 57 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 7 (Day 197)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 197 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

## Table 71: Respiratory Rate (Breaths/min) Post–second Vaccination Compared to Pre–second Vaccination (continued)

**Note:** * P-value based on Kruskal Wallis Test

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Respiratory Rate – breaths per minute | 21 – 23 | 24 – 27 | > 27 | Intubation |

## Table 72: Temperature (°C) Post-first Vaccination Compared to Pre-first Vaccination

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-first vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 2 (Day 8)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 8 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Note:** * P-value based on Kruskal Wallis Test
"xx" represent the value number.

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| **Temperature (oral)** | 38.0 – 38.4°C<br>100.4 – 101.1°F | 38.5 – 38.9°C<br>101.2 – 102.0°F | 39.0 – 40°C<br>102.1 – 104°F | > 40°C<br>> 104°F |

## Table 73: Temperature (°C) Post–second Vaccination Compared to Pre–second Vaccination

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Pre-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| **Post-second vaccination** | | | | |
| n | xx | xx | xx | xx |
| Mean (SD) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) | xx.x (xx.x) |
| Median (q1-q3) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) | xx (xx-xx) |
| Min-Max | xx-xx | xx-xx | xx-xx | xx-xx |
| *p-value = | x.xxx | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and 30 minutes post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 4 (Day 36)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 36 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

**Table 73: Temperature (°C) Post–second Vaccination Compared to Pre–second Vaccination (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Visit 5 (Day 43)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 43 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 6 (Day 57)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 57 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |
| **Visit 7 (Day 197)** | | | | |
| n | | | | |
| Mean (SD) | | | | |
| Median (q1-q3) | | | | |
| Min-Max | | | | |
| *p-value = | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Mild | | | | |
| Moderate | | | | |
| Severe | | | | |
| Potentially life threatening | | | | |
| **Change between pre and Day 197 post vaccination** | | | | |
| Mean of % Difference (95% CI) | | | | |

## Table 73: Temperature (°C) Post–second Vaccination Compared to Pre–second Vaccination (continued)

**Note:** * P-value based on Kruskal Wallis Test
"xx" represent the value number.

| Vital Signs Toxicity Grading | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| **Temperature (oral)** | 38.0 – 38.4°C<br>100.4 – 101.1°F | 38.5 – 38.9°C<br>101.2 – 102.0°F | 39.0 – 40°C<br>102.1 – 104°F | > 40°C<br>> 104°F |

# Appendix 1.G. Physical Examinations

## Table 74: Overall Number of Subject with Abnormal of Any Physical Examination Result after Vaccination

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Overall, n (%)** | | | | |
| General Appearance | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| HEENT | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Cardiovascular | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Respiratory | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Abdomen | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Musculoskeletal | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Extremity/Skin | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Neurological | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| Lymph Nodes | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with one or more abnormal result | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| with no abnormal result | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| **Visit 2 (Day 8)** | | | | |
| General Appearance | | | | |
| HEENT | | | | |
| Cardiovascular | | | | |
| Respiratory | | | | |
| Abdomen | | | | |
| Musculoskeletal | | | | |
| Extremity/Skin | | | | |
| Neurological | | | | |
| Lymph Nodes | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |
| **Visit 4 (Day 36)** | | | | |
| General Appearance | | | | |
| HEENT | | | | |
| Cardiovascular | | | | |
| Abdomen | | | | |
| Musculoskeletal | | | | |
| Extremity/Skin | | | | |
| Neurological | | | | |
| Lymph Nodes | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |
| **Visit 5 (Day 43)** | | | | |
| General Appearance | | | | |
| HEENT | | | | |
| Cardiovascular | | | | |
| Respiratory | | | | |
| Abdomen | | | | |
| Musculoskeletal | | | | |
| Extremity/Skin | | | | |
| Neurological | | | | |
| Lymph Nodes | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |

**Table 74: Overall Number of Subject with Abnormal of Any Physical Examination Result after Vaccination (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Visit 6 (Day 57)** | | | | |
| General Appearance | | | | |
| HEENT | | | | |
| Cardiovascular | | | | |
| Respiratory | | | | |
| Abdomen | | | | |
| Musculoskeletal | | | | |
| Extremity/Skin | | | | |
| Neurological | | | | |
| Lymph Nodes | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |
| **Visit 7 (Day 197)** | | | | |
| General Appearance | | | | |
| HEENT | | | | |
| Cardiovascular | | | | |
| Respiratory | | | | |
| Abdomen | | | | |
| Musculoskeletal | | | | |
| Extremity/Skin | | | | |
| Neurological | | | | |
| Lymph Nodes | | | | |
| with one or more abnormal result | | | | |
| with no abnormal result | | | | |

**Table 75: Physical Examination at Visit 1 Pre-first Vaccination (Day 1)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **General Appearance, n (%)** | | | | |
| Normal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Abnormal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Clinically sig** | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Not done | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **HEENT, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Cardiovascular, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Respiratory, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Abdomen, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Musculoskeletal, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Extremity/Skin, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Neurological, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |

**Table 75: Physical Examination at Visit 1 Pre-first Vaccination (Day 1) (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Lymph Nodes, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Other, n (%)** | | | | |
| ……. | | | | |

**Note:** ** abnormal result with clinically significant.
"xx" represent the value number.

## Table 76: Physical Examination at Visit 2 (Day 8)

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **General Appearance, n (%)** | | | | |
| Normal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Abnormal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Clinically sig** | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Not done | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **HEENT, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Cardiovascular, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Respiratory rate, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Abdomen, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Musculoskeletal, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Extremity/Skin, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Neurological, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |

**Table 76: Physical Examination at Visit 2 (Day 8) (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Lymph Nodes, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Other, n (%)** | | | | |
| …. | | | | |

**Note:** ** abnormal result with clinically significant.
"xx" represent the value number.

**Table 77: Physical Examination at Visit 3 Pre-second Vaccination (Day 29)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **General Appearance, n (%)** | | | | |
| Normal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Abnormal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Clinically sig** | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Not done | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **HEENT, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Cardiovascular, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Respiratory rate, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Abdomen, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Musculoskeletal, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Extremity/Skin, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Neurological, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |

**Table 77: Physical Examination at Visit 3 Pre-second Vaccination (Day 29) (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Lymph Nodes, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Other, n (%)** | | | | |
| …. | | | | |

**Note:** ** abnormal result with clinically significant.
"xx" represent the value number.

## Table 78: Physical Examination at Visit 4 (Day 36)

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **General Appearance, n (%)** | | | | |
| Normal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Abnormal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Clinically sig** | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Not done | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **HEENT, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Cardiovascular, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Respiratory rate, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Abdomen, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Musculoskeletal, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Extremity/Skin, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Neurological, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |

**Table 78: Physical Examination at Visit 4 (Day 36) (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Lymph Nodes, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Other, n (%)** | | | | |
| ……. | | | | |

**Note:** ** abnormal result with clinically significant.
"xx" represent the value number.

## Table 79: Physical Examination at Visit 5 (Day 43)

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **General Appearance, n (%)** | | | | |
| Normal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Abnormal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Clinically sig** | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Not done | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **HEENT, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Cardiovascular, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Respiratory rate, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Abdomen, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Musculoskeletal, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Extremity/Skin, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Neurological, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |

**Table 79: Physical Examination at Visit 5 (Day 43) (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Lymph Nodes, n (%)** | | | | |
| Normal Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Other, n (%)** | | | | |
| …… | | | | |

## Table 80: Physical Examination at Visit 6 (Day 57)

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **General Appearance, n (%)** | | | | |
| Normal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Abnormal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Clinically sig** | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Not done | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **HEENT, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Cardiovascular, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Respiratory rate, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Abdomen, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Musculoskeletal, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Extremity/Skin, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Neurological, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |

**Table 80: Physical Examination at Visit 6 (Day 57) (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Lymph Nodes, n (%)** | | | | |
| Normal Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Other, n (%)** | | | | |
| …… | | | | |

**Note:** ** abnormal result with clinically significant.
"xx" represent the value number.

## Table 81: Physical Examination at Visit 7 (Day 197)

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **General Appearance, n (%)** | | | | |
| Normal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Abnormal | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Clinically sig** | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| Not done | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) | xx (xx.x %) |
| **HEENT, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Cardiovascular, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Respiratory rate, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Abdomen, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Musculoskeletal, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Extremity/Skin, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Neurological, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |

**Table 81: Physical Examination at Visit 7 (Day 197) (continued)**

| | All (N=375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|
| | | 3 µg (N = 125) | 6 µg (N = 125) | |
| **Lymph Nodes, n (%)** | | | | |
| Normal | | | | |
| Abnormal | | | | |
| Clinically sig** | | | | |
| Not done | | | | |
| **Other, n (%)** | | | | |
| …… | | | | |

**Note:** ** abnormal result with clinically significant.
"xx" represent the value number.

# Appendix 1.H. Immunogenicity Analysis - 50% Neutralizing Antibody (NT50)

### Table 82-1: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Full Analysis Population

| $NT_{50}$ Measure | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | GMT (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | GMT (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMT (95% CI) | | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

### Table 82-2: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Full Analysis Population by Age Group

| $NT_{50}$ Measure | | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | 18-59 yr. | GMT (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | GMT (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMT (95% CI) | | | | |
| | ≥ 60 yr. | GMT (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMT (95% CI) | | | | |
| | ≥ 60 yr. | GMT (95% CI) | | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 82-3: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus Stratified by the Receipt of Non-Study COVID-19 Vaccines between Day43 and Day197 in Full Analysis Population**

| $NT_{50}$ Measure | | Received non-study vaccine | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | GMT (95% CI) | Yes | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | | No | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | GMT (95% CI) | Yes | | | | |
| | | No | | | | |
| 6 months after the second vaccination (D197) | GMT (95% CI) | Yes | | | | |
| | | No | | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 82-4: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus between Two Dose Levels of COVIVAC in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **6 µg (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 82-5: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus between COVIVAC Low Dose and AstraZeneca in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 82-6: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus between COVIVAC High Dose and AstraZeneca in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 83-1: Summary of Geometric Mean Concentration (GMC) in IU/mL of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Full Analysis Population**

| $NT_{50}$ Measure | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMC (95% CI) | | | | |

**Note**: $NT_{50}$ GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 83-2: Summary of Geometric Mean Concentration (GMC) in IU/mL of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Full Analysis Population by Age Group**

| $NT_{50}$ Measure | | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | 18-59 yr. | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMC (95% CI) | | | | |
| | ≥ 60 yr. | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMC (95% CI) | | | | |
| | ≥ 60 yr. | GMC (95% CI) | | | | |

**Note**: $NT_{50}$ GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 84-1: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Per Protocol Population**

| $NT_{50}$ Measure | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|
| | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| Baseline (D1) | GMT (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | GMT (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMT (95% CI) | | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 84-2: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Per Protocol Population by Age Group**

| $NT_{50}$ Measure | | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| Baseline (D1) | 18-59 yr. | GMT (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | GMT (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMT (95% CI) | | | | |
| | ≥ 60 yr. | GMT (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMT (95% CI) | | | | |
| | ≥ 60 yr. | GMT (95% CI) | | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 84-3: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus Stratified by the Receipt of Non-Study COVID-19 Vaccines between Day43 and Day197 in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | Received non-study vaccine | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| Baseline (D1) | GMT (95% CI) | Yes | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | | No | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | GMT (95% CI) | Yes | | | | |
| | | No | | | | |
| 6 months after the second vaccination (D197) | GMT (95% CI) | Yes | | | | |
| | | No | | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 84-4: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus between Two Dose Levels of COVIVAC in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **6 µg (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 84-5: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus between COVIVAC Low Dose and AstraZeneca in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 84-6: Summary of Geometric Mean Titer (GMT) of $NT_{50}$ against SARS-CoV-2 Pseudovirus between COVIVAC High Dose and AstraZeneca in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 85-1: Summary of Geometric Mean Concentration (GMC) in IU/mL of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Per Protocol Population**

| $NT_{50}$ Measure | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|
| | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| Baseline (D1) | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMC (95% CI) | | | | |

**Note**: $NT_{50}$ GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 85-2: Summary of Geometric Mean Concentration (GMC) in IU/mL of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Per Protocol Population by Age Group**

| $NT_{50}$ Measure | | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| Baseline (D1) | 18-59 yr. | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMC (95% CI) | | | | |
| | ≥ 60 yr. | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMC (95% CI) | | | | |
| | ≥ 60 yr. | GMC (95% CI) | | | | |

**Note**: $NT_{50}$ GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 86-1: Summary of Geometric Mean Titer Ratio (GMT Ratio) of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Full Analysis Population**

| $NT_{50}$ Measure GMT ratio (95% CI) | COVIVAC | | |
|---|---|---|---|
| | 6 µg / 3 µg | 3 µg / AstraZeneca | 6 µg / AstraZeneca |
| Baseline (D1) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | | | |
| 6 months after the second vaccination (D197) | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 86-2: Summary of Geometric Mean Titer Ratio (GMT Ratio) of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Full Analysis Population by Age Group**

| $NT_{50}$ Measure GMT ratio (95% CI) | | COVIVAC | | |
|---|---|---|---|---|
| | | 6 µg / 3 µg | 3 µg / AstraZeneca | 6 µg / AstraZeneca |
| Baseline (D1) | 18-59 yr. | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | | | |
| | ≥ 60 yr. | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | | | |
| | ≥ 60 yr. | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 87-1: Summary of Geometric Mean Titer Ratio (GMT Ratio) of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Per Protocol Population**

| $NT_{50}$ Measure GMT ratio (95% CI) | COVIVAC | | |
|---|---|---|---|
| | 6 µg / 3 µg | 3 µg / AstraZeneca | 6 µg / AstraZeneca |
| Baseline (D1) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | | | |
| 6 months after the second vaccination (D197) | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 87-2: Summary of Geometric Mean Titer Ratio (GMT Ratio) of $NT_{50}$ against SARS-CoV-2 Pseudovirus in Per Protocol Population by Age Group**

| $NT_{50}$ Measure GMT ratio (95% CI) | | COVIVAC | | |
|---|---|---|---|---|
| | | 6 µg / 3 µg | 3 µg / AstraZeneca | 6 µg / AstraZeneca |
| Baseline (D1) | 18-59 yr. | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | | | |
| | ≥ 60 yr. | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | | | |
| | ≥ 60 yr. | | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 88-1: Summary of Geometric Mean Fold Rise (GMFR) from Baseline of $NT_{50}$ Titers against SARS-CoV-2 Pseudovirus in Full Analysis Population**

| $NT_{50}$ Measure | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | GMFR from baseline (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMFR from baseline (95% CI) | | | | |

**Note**: Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratios of post-vaccination to the pre-first vaccination at D1 (baseline). The analysis included subjects regardless anti S IgG status at baseline.

**Table 88-2: Summary of Geometric Mean Fold Rise (GMFR) from Baseline of $NT_{50}$ Titers against SARS-CoV-2 Pseudovirus in Full Analysis Population by Age Group**

| $NT_{50}$ Measure | | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMFR from baseline (95% CI) | | | | |
| | ≥ 60 yr. | GMFR from baseline (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMFR from baseline (95% CI) | | | | |
| | ≥ 60 yr. | GMFR from baseline (95% CI) | | | | |

**Note**: Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratios of post-vaccination to the pre-first vaccination at D1 (baseline). The analysis included subjects regardless anti S IgG status at baseline.

**Table 89-1: Summary of Geometric Mean Fold Rise (GMFR) from Baseline of $NT_{50}$ Titers against SARS-CoV-2 Pseudovirus in Per Protocol Population**

| $NT_{50}$ Measure | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|
| | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | GMFR from baseline (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMFR from baseline (95% CI) | | | | |

**Note**: Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratios of post-vaccination to the pre-first vaccination at D1 (baseline). The analysis included subjects regardless anti S IgG status at baseline.

**Table 89-2: Summary of Geometric Mean Fold Rise (GMFR) from Baseline of $NT_{50}$ Titers against SARS-CoV-2 Pseudovirus in Per Protocol Population by Age Group**

| $NT_{50}$ Measure | | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMFR from baseline (95% CI) | | | | |
| | ≥ 60 yr. | GMFR from baseline (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMFR from baseline (95% CI) | | | | |
| | 40-59 yr. | GMFR from baseline (95% CI) | | | | |

**Note**: Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratios of post-vaccination to the pre-first vaccination at D1 (baseline). The analysis included subjects regardless anti S IgG status at baseline.

**Table 90-1: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Full Analysis Population**

| $NT_{50}$ Measure ≥ 4-fold (Titer) | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | n (%) (95% CI) | | | | |

**Note**: The 95% CIs are computed via the Clopper-Pearson method.

**Table 90-2: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Full Analysis Population by Age Group**

| | $NT_{50}$ Measure ≥ 4-fold (Titer) | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | 18-59 yr. | n (%) (95% CI) | | | | |
| | ≥ 60 yr. | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | n (%) (95% CI) | | | | |
| | ≥ 60 yr. | n (%) (95% CI) | | | | |

**Note**: The 95% CIs are computed via the Clopper-Pearson method.

**Table 90-3: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus Stratified by the Receipt of Non-Study COVID-19 Vaccines between Day43 and Day197 as defined by a ≥ 4-fold Increase from Baseline in Full Analysis Population**

| $NT_{50}$ Measure ≥ 4-fold | Received non-study vaccine | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | Yes | n (%) (95% CI) | | | | |
| | No | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | Yes | n (%) (95% CI) | | | | |
| | No | n (%) (95% CI) | | | | |

**Note**: The 95% CIs are computed via the Clopper-Pearson method.

**Table 90-4: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline between Two Dose Levels of COVIVAC in Full Analysis Population**

| **$NT_{50}$ Measure ≥ 4-fold (Titer)** | | **COVIVAC** | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI) | **6 µg (N = 125)** n (%) (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 90-5: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline between COVIVAC Low Dose and AstraZeneca in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 90-6: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline between COVIVAC High Dose and AstraZeneca in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 91-1: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Per Protocol Population**

| $NT_{50}$ Measure ≥ 4-fold (Titer) | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|
| | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | n (%) (95% CI) | | | | |

**Note**: The 95% CIs are computed via the Clopper-Pearson method.

**Table 91-2: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Per Protocol Population by Age Group**

| | $NT_{50}$ Measure ≥ 4-fold (Titer) | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | 18-59 yr. | n (%) (95% CI) | | | | |
| | ≥ 60 yr. | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | n (%) (95% CI) | | | | |
| | ≥ 60 yr. | n (%) (95% CI) | | | | |

**Note**: The 95% CIs are computed via the Clopper-Pearson method.

**Table 91-3: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus Stratified by the Receipt of Non-Study COVID-19 Vaccines between Day43 and Day197 as defined by a ≥ 4-fold Increase from Baseline in Per Protocol Analysis Population**

| $NT_{50}$ Measure ≥ 4-fold | Received non-study vaccine | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | Yes | n (%) (95% CI) | | | | |
| | No | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | Yes | n (%) (95% CI) | | | | |
| | No | n (%) (95% CI) | | | | |

**Note**: The 95% CIs are computed via the Clopper-Pearson method.

**Table 91-4: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline between Two Dose Levels of COVIVAC in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI) | **6 µg (N = 125)** n (%) (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 91-5: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline between COVIVAC Low Dose and AstraZeneca in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 91-6: Percentage of Subjects with $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline between COVIVAC High Dose and AstraZeneca in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

# Appendix 1.I. Immunogenicity Analysis – Anti-S IgG Assessed by ELISA

## Table 94-1: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA in Full Analysis Population

| Anti-S IgG Measure (BAU/mL) | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMC (95% CI) | | | | |

**Note**: GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

## Table 94-2: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA in Full Analysis Population by Age Group

| Anti-S IgG Measure (BAU/mL) | | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | 18-59 yr. | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMC (95% CI) | | | | |
| | ≥ 60 yr. | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMC (95% CI) | | | | |
| | ≥ 60 yr. | GMC (95% CI) | | | | |

**Note**: GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 94-3: Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA Stratified by the Receipt of Non-Study COVID-19 Vaccines between Day43 and Day197 in Full Analysis Population**

| Anti-S IgG Measure (BAU/mL) | Received non-study vaccine | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | Yes | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | No | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | Yes | GMC (95% CI) | | | | |
| | No | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | Yes | GMC (95% CI) | | | | |
| | No | GMC (95% CI) | | | | |

**Note**: GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 94-4: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA between Two Dose Levels of COVIVAC in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **6 µg (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 94-5: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA between COVIVAC Low Dose and AstraZeneca in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 94-6: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA between COVIVAC High Dose and AstraZeneca in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 95-1: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA in Per Protocol Population**

| Anti-S IgG Measure | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|
| | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| Baseline (D1) | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMC (95% CI) | | | | |

**Note**: GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 95-2: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA in Per Protocol Population by Age Group**

| Anti-S IgG Measure (BAU/mL) | | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| Baseline (D1) | 18-59 yr. | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMC (95% CI) | | | | |
| | ≥ 60 yr. | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMC (95% CI) | | | | |
| | ≥ 60 yr. | GMC (95% CI) | | | | |

**Note**: GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 95-3: Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA Stratified by the Receipt of Non-Study COVID-19 Vaccines between Day43 and Day197 in Per Protocol Analysis Population**

| Anti-S IgG Measure (BAU/mL) | Received non-study vaccine | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| Baseline (D1) | Yes | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | No | GMC (95% CI) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | Yes | GMC (95% CI) | | | | |
| | No | GMC (95% CI) | | | | |
| 6 months after the second vaccination (D197) | Yes | GMC (95% CI) | | | | |
| | No | GMC (95% CI) | | | | |

**Note**: GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 95-4: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA between Two Dose Levels of COVIVAC in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **6 µg (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 95-5: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA between COVIVAC Low Dose and AstraZeneca in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 95-6: Summary of Geometric Mean Concentration (GMC) in BAU/mL of Anti-S IgG assessed by ELISA between COVIVAC High Dose and AstraZeneca in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 96-1: Summary of Geometric Mean Concentration Ratio (GMC Ratio) of Anti-S IgG assessed by ELISA in Full Analysis Population**

| Anti-S IgG GMC ratio (95% CI) | COVIVAC | | |
|---|---|---|---|
| | 6 µg / 3 µg | 3 µg / AstraZeneca | 6 µg / AstraZeneca |
| Baseline (D1) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | | | |
| 6 months after the second vaccination (D197) | | | |

**Note**: Anti-S IgG GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 96-2: Summary of Geometric Mean Concentration Ratio (GMC Ratio) of Anti-S IgG assessed by ELISA in Full Analysis Population by Age Group**

| Anti-S IgG GMC ratio (95% CI) | | COVIVAC | | |
|---|---|---|---|---|
| | | 6 µg / 3 µg | 3 µg / AstraZeneca | 6 µg / AstraZeneca |
| Baseline (D1) | 18-59 yr. | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | | | |
| | ≥ 60 yr. | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | | | |
| | ≥ 60 yr. | | | |

**Note**: Anti-S IgG GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 97-1: Summary of Geometric Mean Concentration Ratio (GMC Ratio) of Anti-S IgG assessed by ELISA in Per Protocol Population**

| Anti-S IgG GMC ratio (95% CI) | COVIVAC | | |
|---|---|---|---|
| | 6 µg / 3 µg | 3 µg / AstraZeneca | 6 µg / AstraZeneca |
| Baseline (D1) | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | | | |
| 6 months after the second vaccination (D197) | | | |

**Note**: Anti-S IgG GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

**Table 97-2: Summary of Geometric Mean Concentration Ratio (GMC Ratio) of Anti-S IgG assessed by ELISA in Per Protocol Population by Age Group**

| Anti-S IgG GMC ratio (95% CI) | | COVIVAC | | |
|---|---|---|---|---|
| | | 6 µg / 3 µg | 3 µg / AstraZeneca | 6 µg / AstraZeneca |
| Baseline (D1) | 18-59 yr. | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| | ≥ 60 yr. | xx (xx.x- xx.x) | xx (xx.x- xx.x) | xx (xx.x- xx.x) |
| 14 days after the second vaccination (D43) | 18-59 yr. | | | |
| | ≥ 60 yr. | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | | | |
| | ≥ 60 yr. | | | |

**Note**: Anti-S IgG GMCs are analyzed from subjects with seronegative anti-S IgG at baseline.

## Table 98-1: Summary of Geometric Mean Fold Rise (GMFR) from Baseline of Anti-S IgG Concentration assessed by ELISA in Full Analysis Population

| Anti-S IgG Measure | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | GMFR from baseline (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMFR from baseline (95% CI) | | | | |

**Note**: Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratios of post-vaccination to the pre-first vaccination at D1 (baseline).

## Table 98-2: Summary of Geometric Mean Fold Rise (GMFR) from Baseline of Anti-S IgG Concentration assessed by ELISA in Full Analysis Population by Age Group

| Anti-S IgG Measure | | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMFR from baseline (95% CI) | | | | |
| | ≥ 60 yr. | GMFR from baseline (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMFR from baseline (95% CI) | | | | |
| | ≥ 60 yr. | GMFR from baseline (95% CI) | | | | |

**Note**: Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratios of post-vaccination to the pre-first vaccination at D1 (baseline).

## Table 99-1: Summary of Geometric Mean Fold Rise (GMFR) from Baseline of Anti-S IgG Concentration assessed by ELISA in Per Protocol Population

| Anti-S IgG Measure | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|
| | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | GMFR from baseline (95% CI) | | | | |
| 6 months after the second vaccination (D197) | GMFR from baseline (95% CI) | | | | |

**Note**: Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratios of post-vaccination to the pre-first vaccination at D1 (baseline).

## Table 99-2: Summary of Geometric Mean Fold Rise (GMFR) from Baseline of Anti-S IgG Concentration assessed by ELISA in Per Protocol Population by Age Group

| Anti-S IgG Measure | | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | 18-59 yr. | GMFR from baseline (95% CI) | | | | |
| | ≥ 60 yr. | GMFR from baseline (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | GMFR from baseline (95% CI) | | | | |
| | ≥ 60 yr. | GMFR from baseline (95% CI) | | | | |

**Note**: Geometric Mean Fold Rise (GMFR) is the geometric mean of the ratios of post-vaccination to the pre-first vaccination at D1 (baseline).

**Table 100-1: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Full Analysis Population**

| Anti-S IgG Measure ≥ 4-fold | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | n (%) (95% CI) | | | | |

**Note**: The 95% CIs were computed via the Clopper-Pearson method.

**Table 100-2: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Full Analysis Population by Age Group**

| Anti-S IgG Measure ≥ 4-fold | | | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| 14 days after the second vaccination (D43) | 18-59 yr. | n (%) (95% CI) | | | | |
| | ≥ 60 yr. | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | n (%) (95% CI) | | | | |
| | ≥ 60 yr. | n (%) (95% CI) | | | | |

**Note**: The 95% CIs were computed via the Clopper-Pearson method.

**Table 100-3: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA Stratified by the Receipt of Non-Study COVID-19 Vaccines between Day43 and Day197as defined by a ≥ 4-fold Increase from Baseline in Full Analysis Population**

| Anti-S IgG Measure ≥ 4-fold | Received non-study vaccine | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | Yes | n (%) (95% CI) | | | | |
| | No | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | Yes | n (%) (95% CI) | | | | |
| | No | n (%) (95% CI) | | | | |

**Note**: The 95% CIs were computed via the Clopper-Pearson method.

**Table 100-4: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline between Two Dose Levels of COVIVAC in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI) | **6 µg (N = 125)** n (%) (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 100-5: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline between COVIVAC Low Dose and AstraZeneca in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 100-6: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline between COVIVAC High Dose and AstraZeneca in Full Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 101-1: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Per Protocol Population**

| Anti-S IgG Measure ≥ 4-fold | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|
| | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | n (%) (95% CI) | | | | |

**Note**: The 95% CIs were computed via the Clopper-Pearson method.

**Table 101-2: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Per Protocol Population by Age Group**

| Anti-S IgG Measure ≥ 4-fold | | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | 18-59 yr. | n (%) (95% CI) | | | | |
| | ≥ 60 yr. | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | 18-59 yr. | n (%) (95% CI) | | | | |
| | ≥ 60 yr. | n (%) (95% CI) | | | | |

**Note**: The 95% CIs were computed via the Clopper-Pearson method.

**Table 101-3: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA Stratified by the Receipt of Non-Study COVID-19 Vaccines between Day43 and Day197as defined by a ≥ 4-fold Increase from Baseline in Per Protocol Analysis Population**

| Anti-S IgG Measure ≥ 4-fold | Received non-study vaccine | | All (N = xxx) | COVIVAC | | AstraZeneca (N = xxx) |
|---|---|---|---|---|---|---|
| | | | | 3 µg (N = xxx) | 6 µg (N = xxx) | |
| 14 days after the second vaccination (D43) | Yes | n (%) (95% CI) | | | | |
| | No | n (%) (95% CI) | | | | |
| 6 months after the second vaccination (D197) | Yes | n (%) (95% CI) | | | | |
| | No | n (%) (95% CI) | | | | |

**Note**: The 95% CIs were computed via the Clopper-Pearson method.

**Table 101-4: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline between Two Dose Levels of COVIVAC in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** n (%) (95% CI) | **6 µg (N = 125)** n (%) (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 101-5: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline between COVIVAC Low Dose and AstraZeneca in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **3 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

**Table 101-6: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline between COVIVAC High Dose and AstraZeneca in Per Protocol Analysis Population**

| $NT_{50}$ Measure | | COVIVAC | |
|---|---|---|---|
| | | **6 µg (N = 125)** GMT (95% CI) | **AstraZeneca (N = 125)** GMT (95% CI) |
| **Baseline (D1)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **14 days after the second vaccination (D43)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| **6 months after the second vaccination (D197)** | | | |
| All | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| 18-59 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |
| ≥ 60 years | | xx (xx.x%) (xx.x-xx.x) | xx (xx.x%) (xx.x-xx.x) |
| | p-value = | | |

**Note**: $NT_{50}$ GMTs are analyzed from subjects with seronegative anti-S IgG at baseline.
The two-sided 95% Miettinen and Nurminen confidence intervals will be used for the rate difference
The two-sided Fisher exact test will be used for p-value.

# Appendix 1.J. Immunogenicity Analysis – S Protein- Specific T Cell-Mediated Immunity (CMI) by ELISpot assay

## Table 104: IFN-gamma, Descriptive by Follow up Visit and Vaccination Groups in Full Analysis Population

| IFN-gamma (SFU/1x10$^6$ cells) | | All | NDV-HXP-S | AstraZeneca | 3 µg | 6 µg |
|---|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx | |
| | Median | xx | xx | xx | xx | |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx | |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx | |
| | *p-value = | | x.xxx | x.xxx | | |
| 14 days after the second vaccination (D43) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | | | | |
| 6 months after the second vaccination (D197) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | | | | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | | |
| Baseline (D1) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | | | | |
| 14 days after the second vaccination (D43) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | x.xxx | x.xxx | | |
| 6 months after the second vaccination (D197) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | x.xxx | x.xxx | | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 104-1: IFN-gamma, Descriptive by Follow up Visit and Vaccination Groups in Age group 18-59 Years in Full Analysis Population**

| IFN-gamma (SFU/1x10$^6$ cells) | | All | NDV-HXP-S$_{AstraZeneca}$ 3 µg | 6 µg |
|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx |
| | *p-value = | | x.xxx | x.xxx |
| 14 days after the second vaccination (D43) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 6 months after the second vaccination (D197) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| **SARS-CoV-2 vial 2 - DMSO** | | | | |
| Baseline (D1) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 14 days after the second vaccination (D43) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 6 months after the second vaccination (D197) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 104-2: IFN-gamma, Descriptive by Follow up Visit and Vaccination Groups in Age group ≥ 60 Years in Full Analysis Population**

| IFN-gamma (SFU/1x10$^6$ cells) | | All | NDV-HXP-S | AstraZeneca | 3 µg | 6 µg |
|---|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx | |
| | Median | xx | xx | xx | xx | |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx | |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx | |
| | *p-value = | | x.xxx | x.xxx | | |
| 14 days after the second vaccination (D43) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | x.xxx | x.xxx | | |
| 6 months after the second vaccination (D197) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | x.xxx | x.xxx | | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | | |
| Baseline (D1) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | x.xxx | x.xxx | | |
| 14 days after the second vaccination (D43) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | x.xxx | x.xxx | | |
| 6 months after the second vaccination (D197) | n | | | | | |
| | Median | | | | | |
| | 95% CI for Median | | | | | |
| | Min-Max | | | | | |
| | *p-value = | | x.xxx | x.xxx | | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 105: IL5, Descriptive by Follow up Visit and Vaccination Groups in Full Analysis Population**

| IL5 (SFU/1x10$^6$ cells) | | All | NDV-HXP-S 6 µg | AstraZeneca 3 µg | |
|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx |
| | *p-value = | | | | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 105-1: IL5, Descriptive by Follow up Visit and Vaccination Groups in Age group 18-59 Years in Full Analysis Population**

| IL5 (SFU/1x10$^6$ cells) | | All | NDV-HXP-S 3 µg | AstraZeneca 6 µg | |
|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx |
| | *p-value = | | x.xxx | x.xxx | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 105-2: IL5, Descriptive by Follow up Visit and Vaccination Groups in Age group ≥ 60 Years in Full Analysis Population**

| IL5 (SFU/1x10$^6$ cells) | | All | NDV-HXP-S | AstraZeneca 3 µg | 6 µg |
|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx |
| | *p-value = | | x.xxx | x.xxx | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 106: IFN-gamma / IL5 ratios, Descriptive by Visit and Vaccination Groups in Full Analysis Population**

| IFN-gamma / IL5 ratios | | All | NDV-HXP-S 6 µg | AstraZeneca 3 µg | |
|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min - Max | xx - xx | xx - xx | xx - xx | xx - xx |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |

**Table 107: IFN-gamma, Descriptive by Follow up Visit and Vaccination Groups in Per Protocol Analysis Population**

| IFN-gamma (SFU/1x10$^6$ cells) | | All | NDV-HXP-S$_{AstraZeneca}$ 3 µg | 6 µg | |
|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx |
| | *p-value = | | | | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 107-1: IFN-gamma, Descriptive by Follow up Visit and Vaccination Groups in Age group 18-59 Years in Per Protocol Analysis Population**

| IFN-gamma (SFU/1x10$^6$ cells) | | All | NDV-HXP-S$_{AstraZeneca}$ 3 µg | 6 µg |
|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx |
| | *p-value = | | x.xxx | x.xxx |
| 14 days after the second vaccination (D43) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 6 months after the second vaccination (D197) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| **SARS-CoV-2 vial 2 - DMSO** | | | | |
| Baseline (D1) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 14 days after the second vaccination (D43) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 6 months after the second vaccination (D197) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 107-2: IFN-gamma, Descriptive by Follow up Visit and Vaccination Groups in Age group ≥ 60 Years in Per Protocol Analysis Population**

| IFN-gamma (SFU/1x10$^6$ cells) | | All | NDV-HXP-S$_{AstraZeneca}$ 3 µg | 6 µg |
|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx |
| | *p-value = | | x.xxx | x.xxx | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 108: IL5, Descriptive by Follow up Visit and Vaccination Groups in Per Protocol Analysis Population**

| IL5 (SFU/1x10⁶ cells) | | All | NDV-HXP-S 6 µg | AstraZeneca 3 µg | |
|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx |
| | *p-value = | | | | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | | | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 108-1: IL5, Descriptive by Follow up Visit and Vaccination Groups in Age group 18-59 Years in Per Protocol Analysis Population**

| IL5 (SFU/1x10$^6$ cells) | | All | NDV-HXP-S 3 µg | AstraZeneca 6 µg |
|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx |
| | *p-value = | | x.xxx | x.xxx |
| 14 days after the second vaccination (D43) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 6 months after the second vaccination (D197) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| **SARS-CoV-2 vial 2 - DMSO** | | | | |
| Baseline (D1) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 14 days after the second vaccination (D43) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |
| 6 months after the second vaccination (D197) | n | | | |
| | Median | | | |
| | 95% CI for Median | | | |
| | Min-Max | | | |
| | *p-value = | | x.xxx | x.xxx |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 108-2: IL5, Descriptive by Follow up Visit and Vaccination Groups in Age group ≥ 60 Years in Per Protocol Analysis Population**

| IL5 (SFU/1x10$^6$ cells) | | All | NDV-HXP-S 6 µg | AstraZeneca 3 µg | |
|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min-Max | xx - xx | xx - xx | xx - xx | xx - xx |
| | *p-value = | | x.xxx | x.xxx | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| | *p-value = | | x.xxx | x.xxx | |

**Note**: *Comparing between COVIVAC vaccine to AstraZeneca

**Table 109: IFN-gamma / IL5 ratios, Descriptive by Visit and Vaccination Groups in Per Protocol Analysis Population**

| IFN-gamma / IL5 ratios | | All | NDV-HXP-S µg | AstraZeneca 3 µg | 6 |
|---|---|---|---|---|---|
| **SARS-CoV-2 vial 1 - DMSO** | | | | | |
| Baseline (D1) | n | n = xx | n = xx | n = xx | n = xx |
| | Median | xx | xx | xx | xx |
| | 95% CI for Median | xx - xx | xx - xx | xx - xx | xx - xx |
| | Min - Max | xx - xx | xx - xx | xx - xx | xx - xx |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| **SARS-CoV-2 vial 2 - DMSO** | | | | | |
| Baseline (D1) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| 14 days after the second vaccination (D43) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |
| 6 months after the second vaccination (D197) | n | | | | |
| | Median | | | | |
| | 95% CI for Median | | | | |
| | Min-Max | | | | |

# Appendix 1.K. Concomitant Medication

## Table 110: Concomitant Medication by Pharmacological Class According to WHO DD

| Anatomical Main Group | Therapeutic Subgroup | All (N = 375) | COVIVAC | | AstraZeneca (N = 125) |
|---|---|---|---|---|---|
| | | | 3 µg (N = 125) | 6 µg (N = 125) | |
| All | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| ATC 1 | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| ATC 2 | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |
| ATC 3 | | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) | xx (xx.x%) |

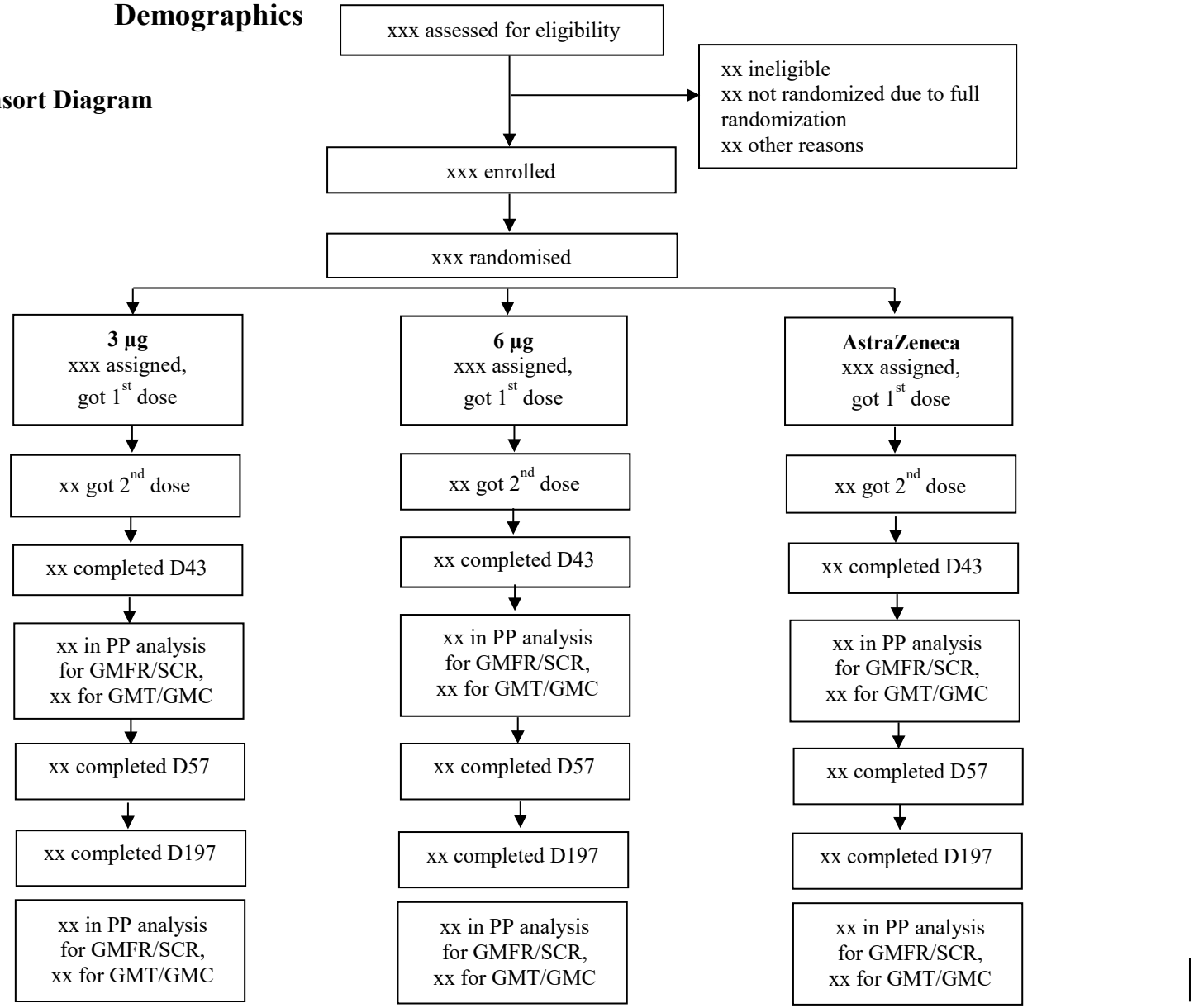
**Note**: Number of subject with at least one concomitant medication in a given pharmacological class

# APPENDIX 2. FIGURES

## LIST OF FIGURES

# Appendix 2.A. Demographics

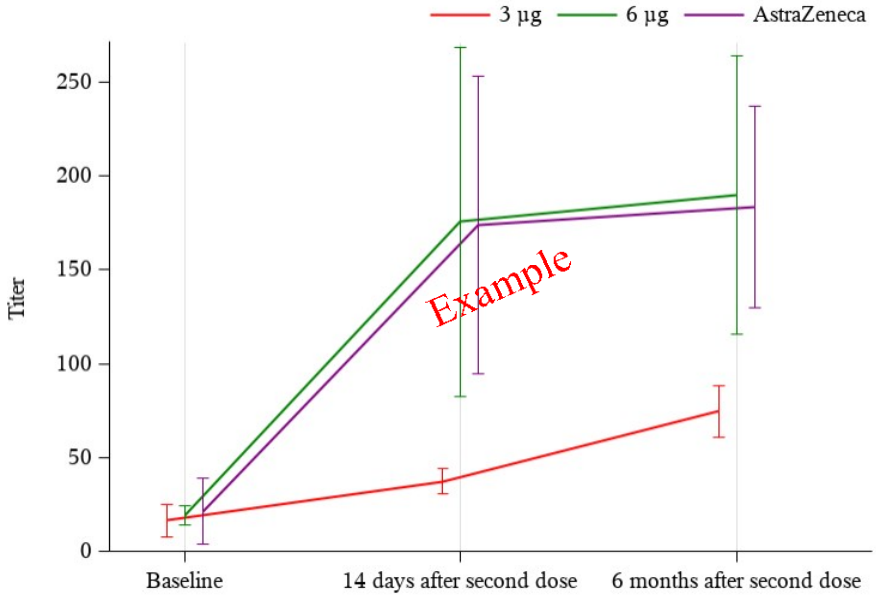
**Figure 1: Consort Diagram**



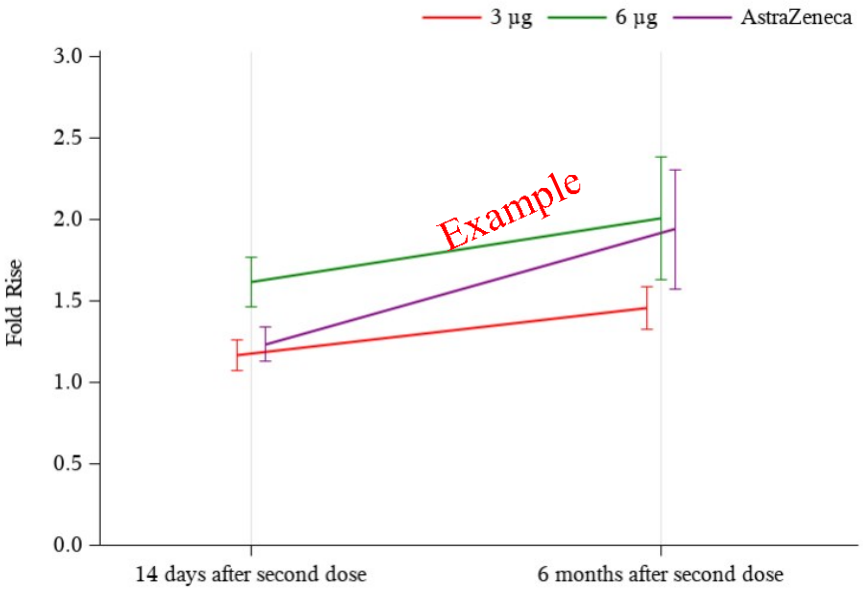
# Appendix 2.B. Immunogenicity - Geometric Mean Titer (GMT), Geometric Mean Fold Rise (GMFR)

**Figure 2: Geometric Mean Titer (GMT), Geometric Mean Fold Rise (GMFR) of NT50 against SARS-CoV-2 Pseudovirus in Full Analysis Population**

Mock data was used to prepare the dummy plot. Value of y axis is not the real scale.



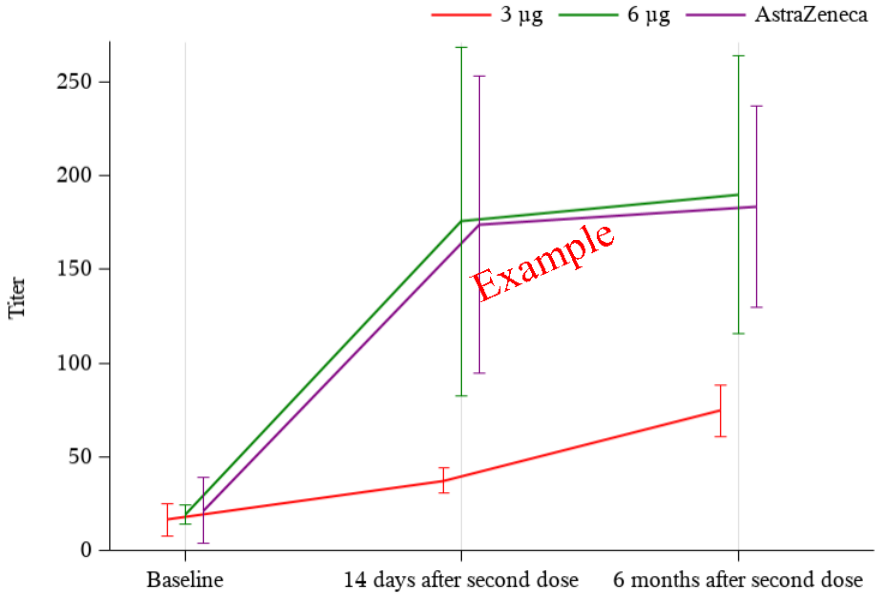

**Bars represent geometric mean titer and 95% CI**



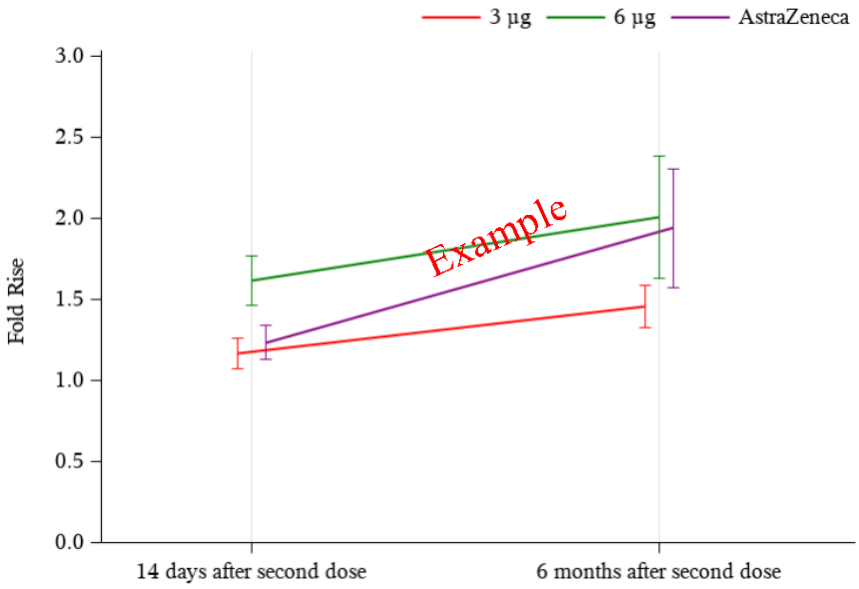

**Bars represent geometric mean fold-rise (GMFR) and 95% CI**

**Figure 2-1: Geometric Mean Titer (GMT), Geometric Mean Fold Rise (GMFR) of NT50 against SARS-CoV-2 Pseudovirus in Age 18-59 Years in Full Analysis Population**

Mock data was used to prepare the dummy plot. Value of y axis is not the real scale.



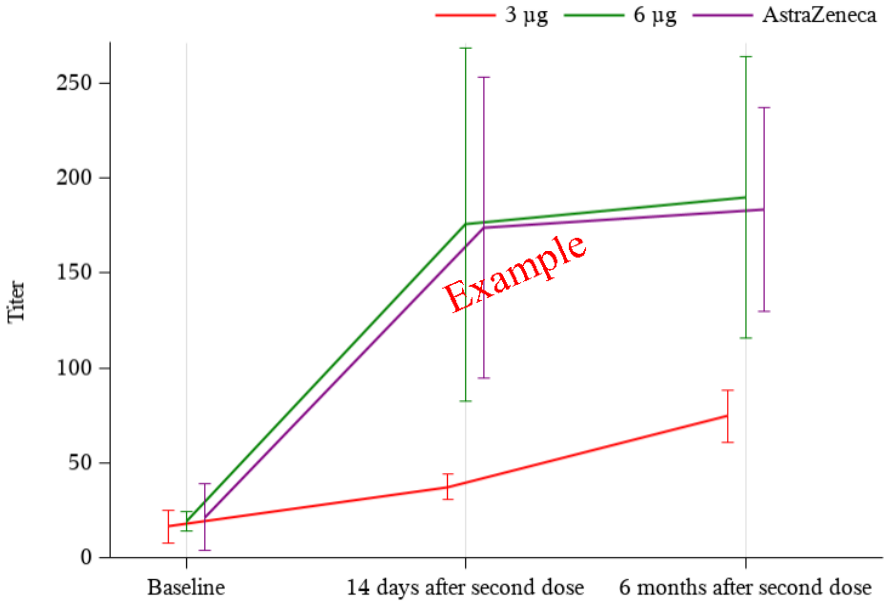

**Bars represent geometric mean titer and 95% CI**



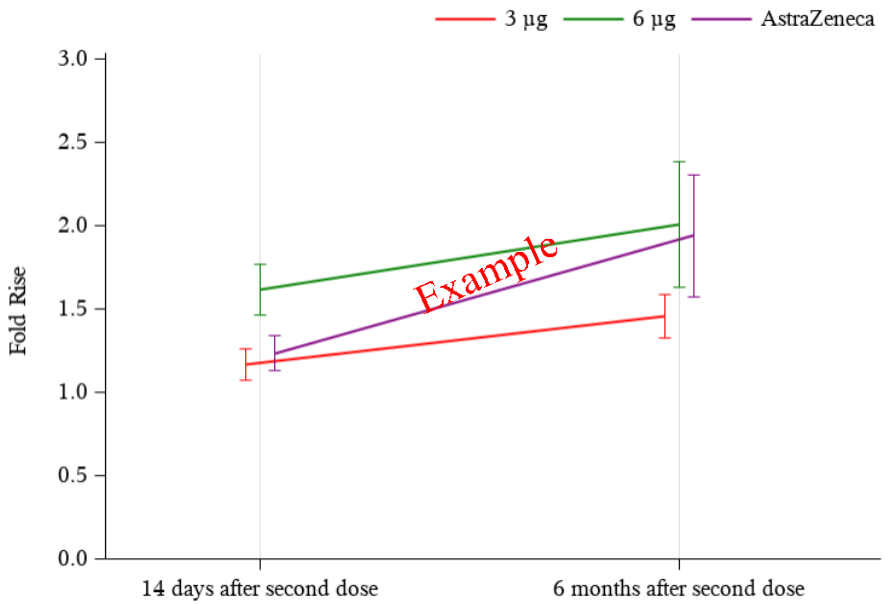

**Bars represent geometric mean fold-rise (GMFR) and 95% CI**

**Figure 2-2: Geometric Mean Titer (GMT), Geometric Mean Fold Rise (GMFR) of NT50 against SARS-CoV-2 Pseudovirus in Age ≥ 60 Years in Full Analysis Population**

Mock data was used to prepare the dummy plot. Value of y axis is not the real scale.




**Bars represent geometric mean titer and 95% CI**




**Bars represent geometric mean fold-rise (GMFR) and 95% CI**

**Figure 3: Geometric Mean Titer (GMT), Geometric Mean Fold Rise (GMFR) of NT50 against SARS-CoV-2 Pseudovirus in Per Protocol Analysis Population**

**Figure 3-1: Geometric Mean Titer (GMT), Geometric Mean Fold Rise (GMFR) of NT50 against SARS-CoV-2 Pseudovirus in Age 18-59 Years in Per Protocol Analysis Population**

**Figure 3-2: Geometric Mean Titer (GMT), Geometric Mean Fold Rise (GMFR) of NT50 against SARS-CoV-2 Pseudovirus in Age ≥ 60 Years in Per Protocol Analysis Population**

**Figure 4: Geometric Mean Concentration (GMC), Geometric Mean Fold Rise (GMFR) of Anti-S IgG assessed by ELISA in Full Analysis Population**

**Figure 4-1: Geometric Mean Concentration (GMC), Geometric Mean Fold Rise (GMFR) of Anti-S IgG assessed by ELISA in Age 18-59 Years in Full Analysis Population**

**Figure 4-2: Geometric Mean Concentration (GMC), Geometric Mean Fold Rise (GMFR) of Anti-S IgG assessed by ELISA in Age ≥ 60 Years in Full Analysis Population**

**Figure 5: Geometric Mean Concentration (GMC), Geometric Mean Fold Rise (GMFR) of Anti-S IgG assessed by ELISA in Per Protocol Analysis Population**

**Figure 5-1: Geometric Mean Concentration (GMC), Geometric Mean Fold Rise (GMFR) of Anti-S IgG assessed by ELISA in Age 18-59 Years in Per Protocol Analysis Population**

**Figure 5-2: Geometric Mean Concentration (GMC), Geometric Mean Fold Rise (GMFR) of Anti-S IgG assessed by ELISA in Age ≥ 60 Years in Per Protocol Analysis Population**

Line plot will be presented for all figure of GMT, GMFR and 95% CI.

# Appendix 2.C. Immunogenicity - Seroresponses

**Figure 6: $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Full Analysis Population**

Mock data was used to prepare the dummy plot. Value of y axis is not the real scale.

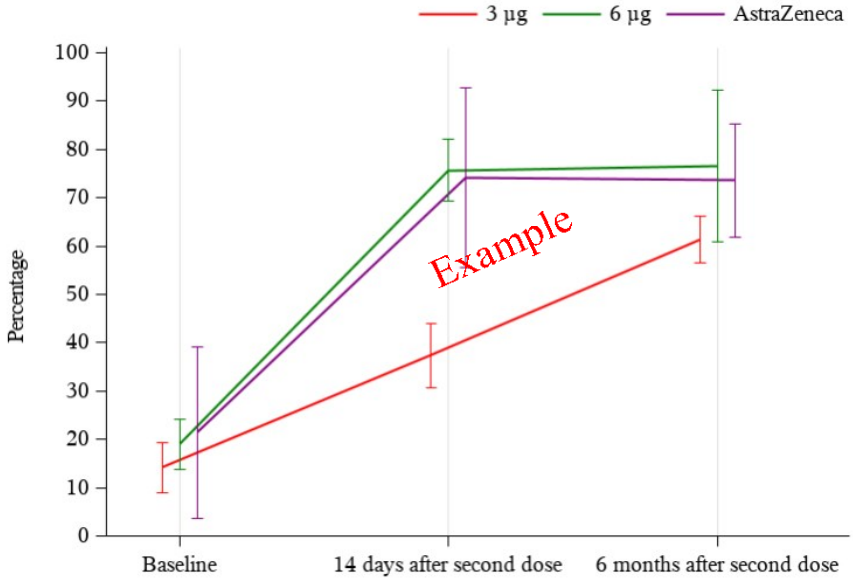



**Figure 6-1: $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Age 18-59 Years in Full Analysis Population**

Mock data was used to prepare the dummy plot. Value of y axis is not the real scale.

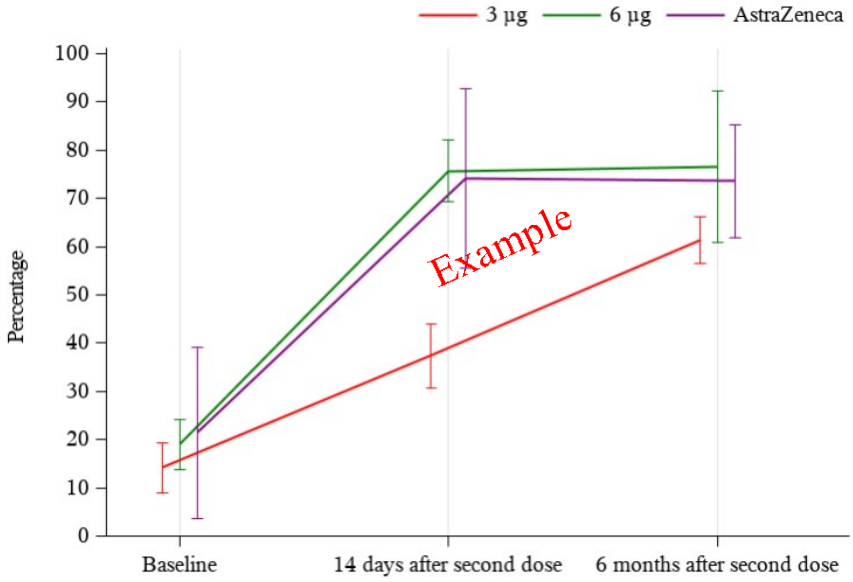


**Figure 6-2: $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Age ≥ 60 Years in Full Analysis Population**

Mock data was used to prepare the dummy plot. Value of y axis is not the real scale.

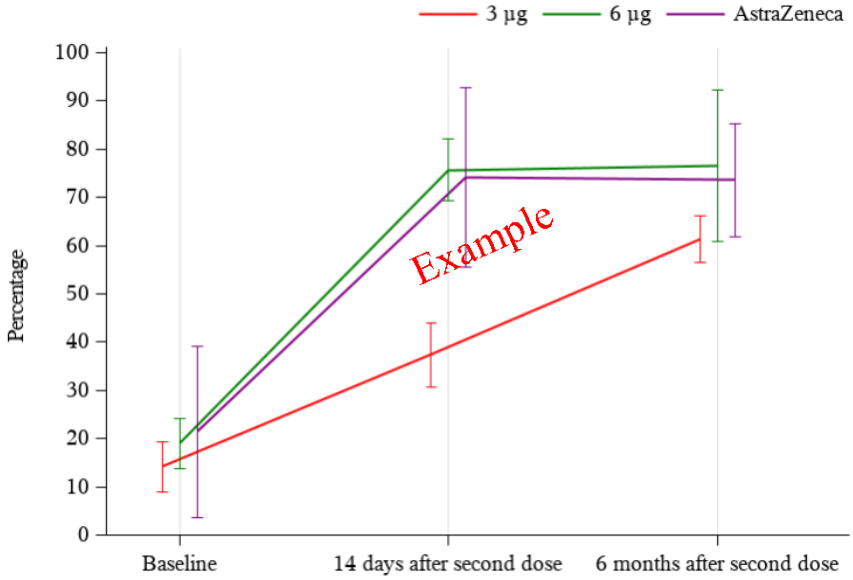



**Figure 7: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Per Protocol Analysis Population**

**Figure 7-1: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Age 18-59 Years in Per Protocol Analysis Population**

**Figure 7-2: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 4-fold Increase from Baseline in Age ≥ 60 Years in Per Protocol Analysis Population**

**Figure 8: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 10-fold Increase from Baseline in Full Analysis Population**

**Figure 8-1: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 10-fold Increase from Baseline in Age 18-59 Years in Full Analysis Population**

**Figure 8-2: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 10-fold Increase from Baseline in Age ≥ 60 Years in Full Analysis Population**

**Figure 9: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 10-fold Increase from Baseline in Per Protocol Analysis Population**

**Figure 9-1: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 10-fold Increase from Baseline in Age 18-59 Years in Per Protocol Analysis Population**

**Figure 9-2: Percentage of Subjects with $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus as defined by a ≥ 10-fold Increase from Baseline in Age ≥ 60 Years in Per Protocol Analysis Population**

**Figure 10: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Full Analysis Population**

**Figure 10-1: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Age 18-59 Years in Full Analysis Population**

**Figure 10-2: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Age ≥ 60 Years in Full Analysis Population**

**Figure 11: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Per Protocol Analysis Population**

**Figure 11-1: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Age 18-59 Years in Per Protocol Analysis Population**

**Figure 11-2: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 4-fold Increase from Baseline in Age ≥ 60 Years in Per Protocol Analysis Population**

**Figure 12: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 10-fold Increase from Baseline in Full Analysis Population**

**Figure 12-1: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 10-fold Increase from Baseline in Age 18-59 Years in Full Analysis Population**

**Figure 12-2: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 10-fold Increase from Baseline in Age ≥ 60 Years in Full Analysis Population**

**Figure 13: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 10-fold Increase from Baseline in Per Protocol Analysis Population**

**Figure 13-1: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 10-fold Increase from Baseline in Age 18-59 Years in Per Protocol Analysis Population**

**Figure 13-2: Percentage of Subjects with Seroresponses in Anti-S IgG Concentration assessed by ELISA as defined by a ≥ 10-fold Increase from Baseline in Age ≥ 60 Years in Per Protocol Analysis Population**

# Appendix 2.E. Immunogenicity – Reverse Cumulative

**Figure 14: $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus Reverse Cumulative Distribution Curves in Full Analysis Population**

Mock data was used to prepare the dummy plot. Value of y axis is not the real scale.

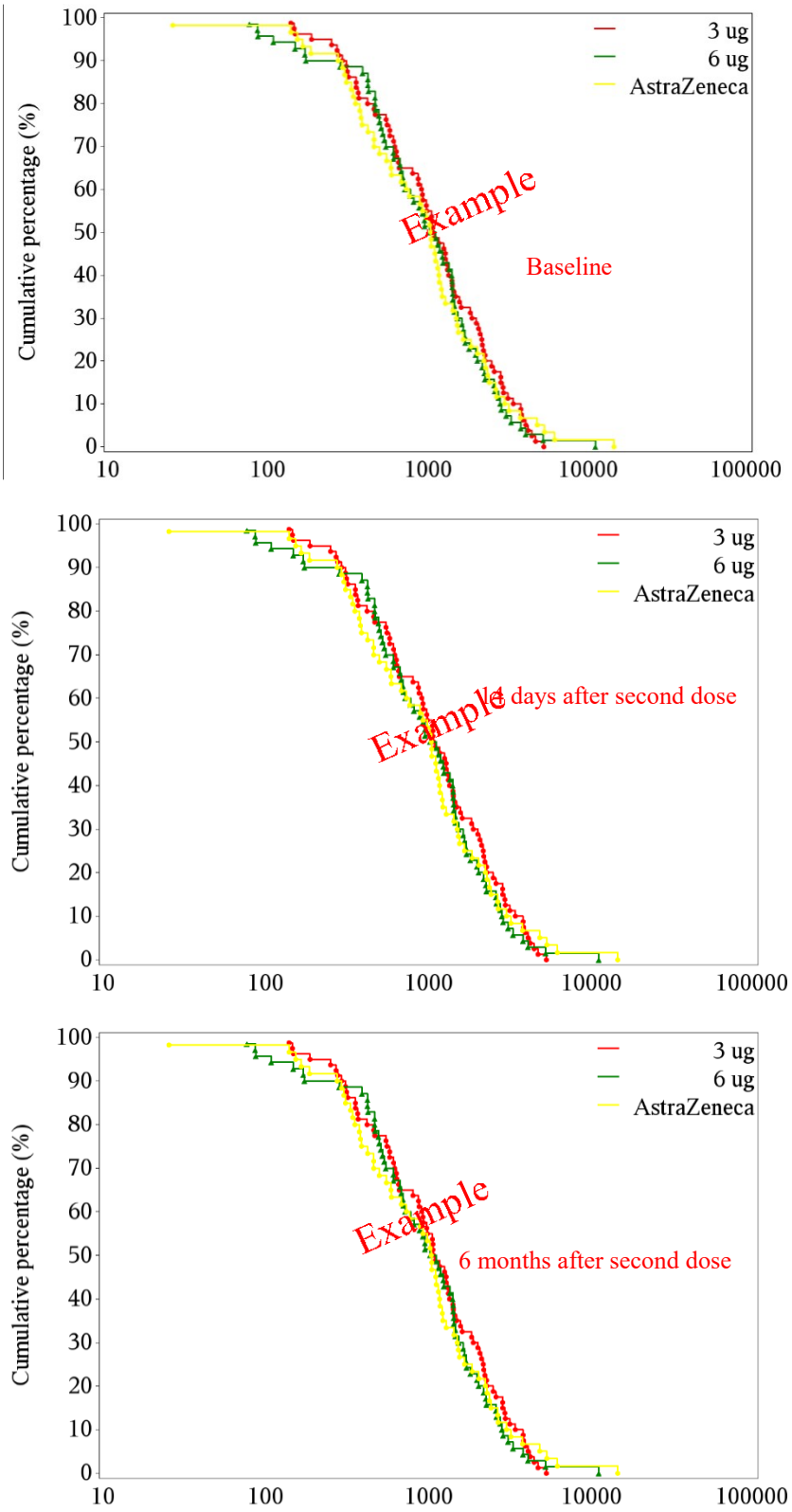


**Figure 14-1: $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus Reverse Cumulative Distribution Curves in Age 18-59 Years in Full Analysis Population**

**Figure 14-2: $NT_{50}$ Seroresponses against SARS-CoV-2 Pseudovirus Reverse Cumulative Distribution Curves in Age ≥ 60 Years in Full Analysis Population**

**Figure 15: $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus Reverse Cumulative Distribution Curves in Per Protocol Analysis Population**

**Figure 15-1: $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus Reverse Cumulative Distribution Curves in Age 18-59 Years in Per Protocol Analysis Population**

**Figure 15-2: $NT_{50}$ Titer Seroresponses against SARS-CoV-2 Pseudovirus Reverse Cumulative Distribution Curves in Age ≥ 60 Years in Per Protocol Analysis Population**

**Figure 16: Anti-S IgG Concentration Assessed by ELISA Reverse Cumulative Distribution Curves in Full Analysis Population**

**Figure 16-1: Anti-S IgG Concentration Assessed by ELISA Reverse Cumulative Distribution Curves in Age 18-59 Years in Full Analysis Population**

**Figure 16-2: Anti-S IgG Concentration Assessed by ELISA Reverse Cumulative Distribution Curves in Age ≥ 60 Years in Full Analysis Population**

**Figure 17: Anti-S IgG Concentration Assessed by ELISA Reverse Cumulative Distribution Curves in Per Protocol Analysis Population**

**Figure 17-1: Anti-S IgG Concentration Assessed by ELISA Reverse Cumulative Distribution Curves in Age 18-59 Years in Per Protocol Analysis Population**

**Figure 17-2: Anti-S IgG Concentration Assessed by ELISA Reverse Cumulative Distribution Curves in Age ≥ 60 Years in Per Protocol Analysis Population**

# Appendix 2.F. Immunogenicity – S protein-specific T cell

**Figure 18: IFN-gamma (ELISpot SFU/1x10$^6$ cells), Median and 95% Confidence Interval by Vial, Follow up Visit and Vaccination Groups in Full Analysis Population**

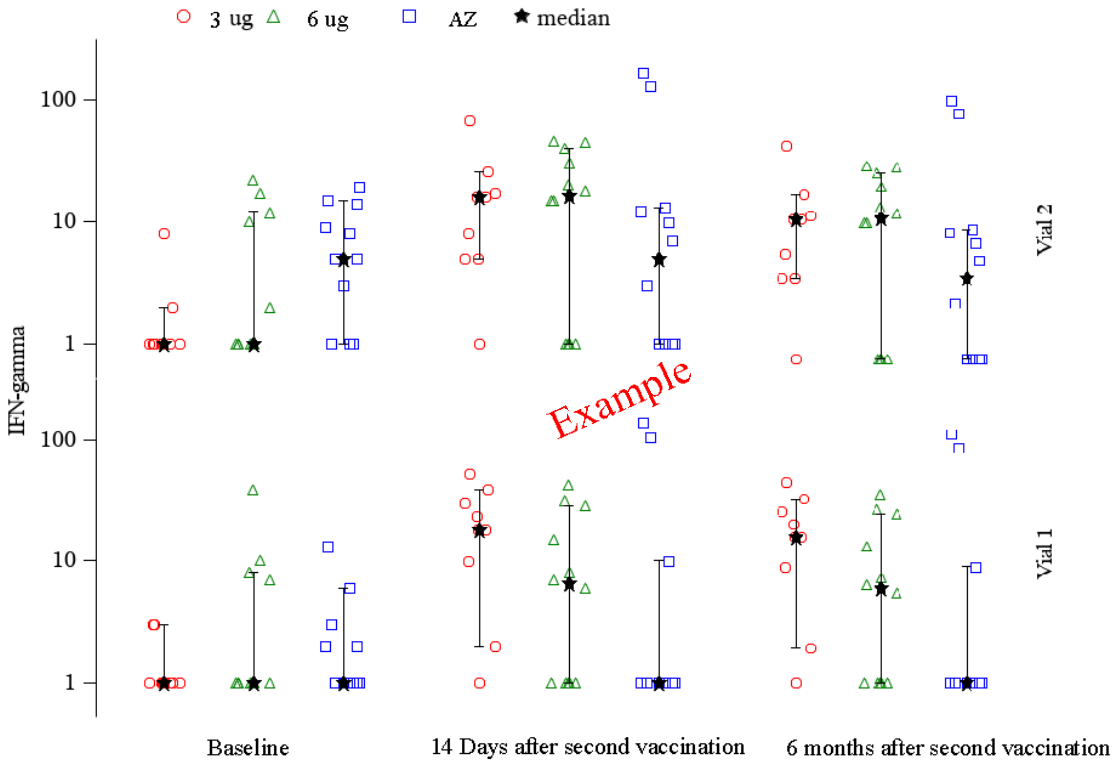


**Figure 19: IL5 (ELISpot SFU/1x10$^6$ cells), Median and 95% Confidence Interval by Vial, Follow up Visit and Vaccination Groups in Full Analysis Population**

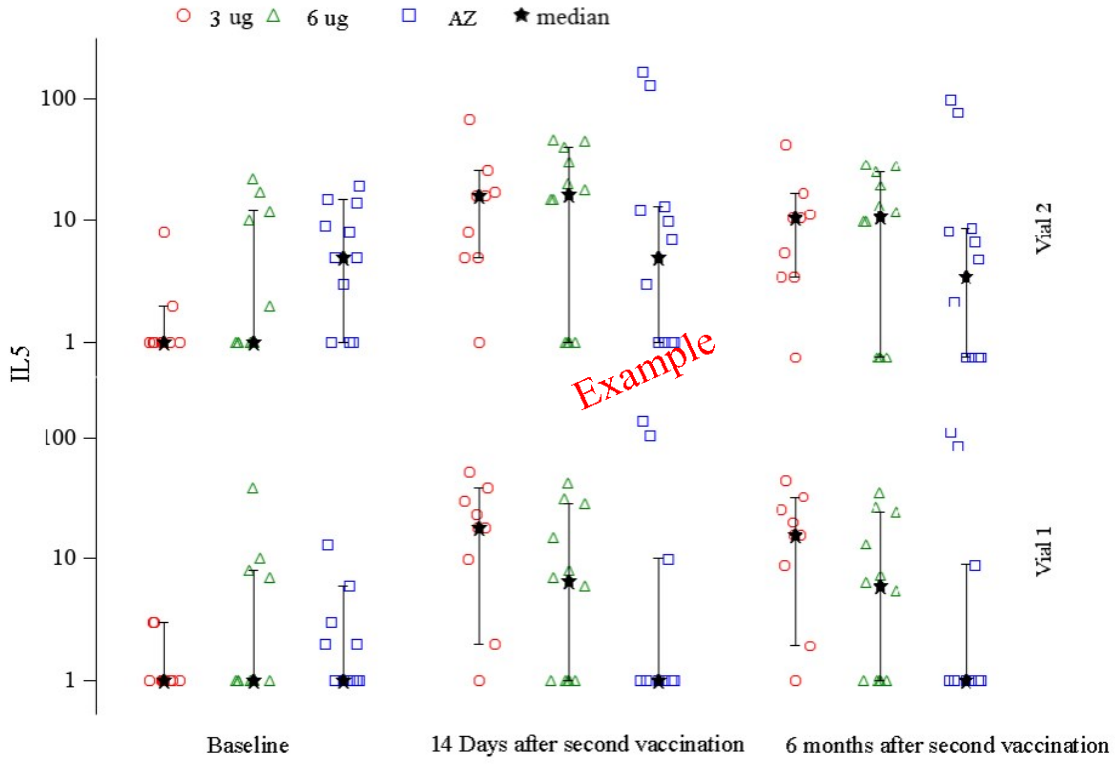


**Figure 20: IFN- gamma/IL5 Ratios, Median and 95% Confidence Interval by Vial, Follow up Visit and Vaccination Groups in Full Analysis Population**

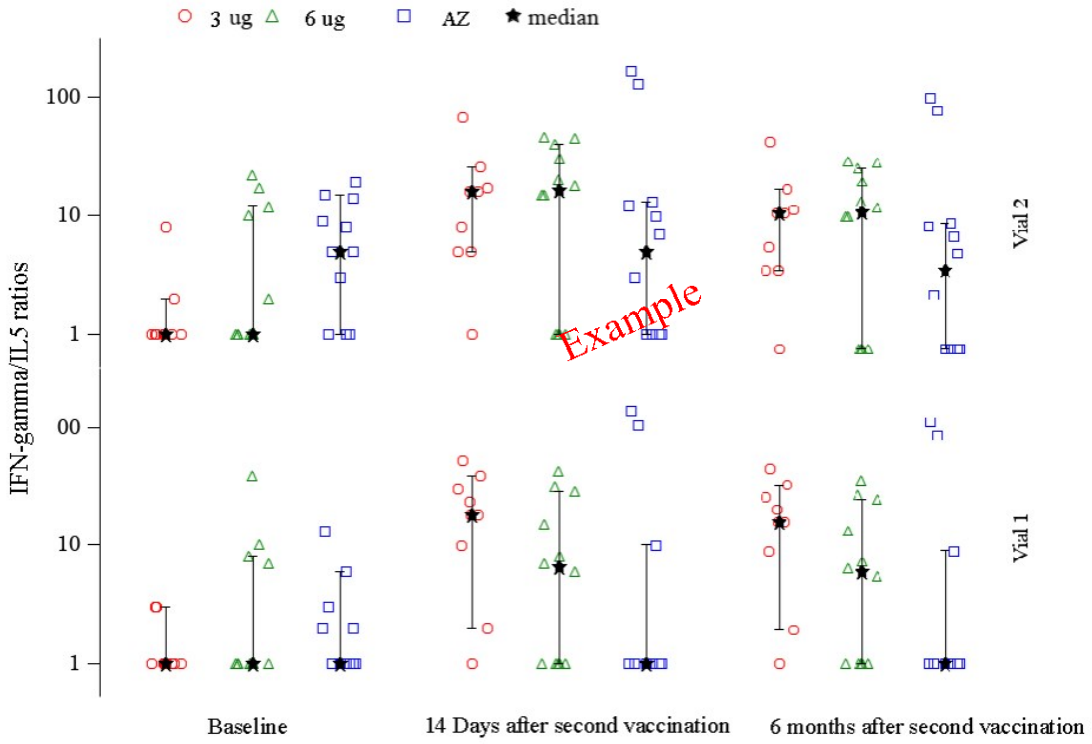


**Figure 21: IFN-gamma (ELISpot SFU/1x10$^6$ cells), Median and 95% Confidence Interval by Vial, Follow up Visit and Vaccination Groups in Per Protocol Analysis Population**

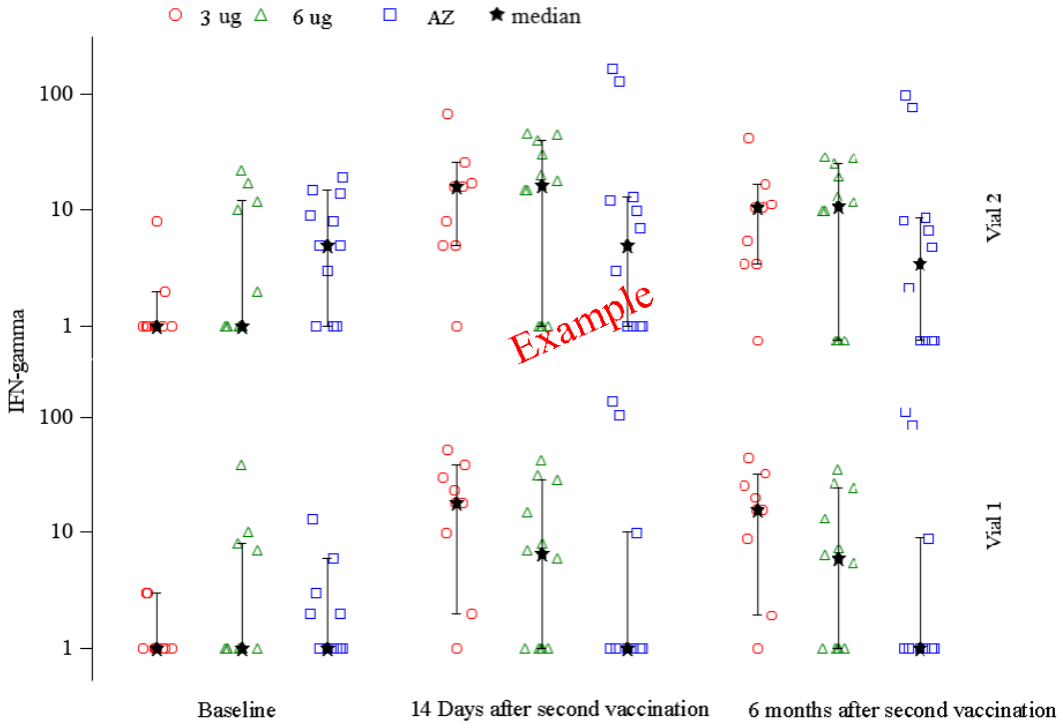



**Figure 22: IL5 (ELISpot SFU/1x10$^6$ cells), Median and 95% Confidence Interval by Vial, Follow up Visit and Vaccination Groups in Per Protocol Analysis Population**

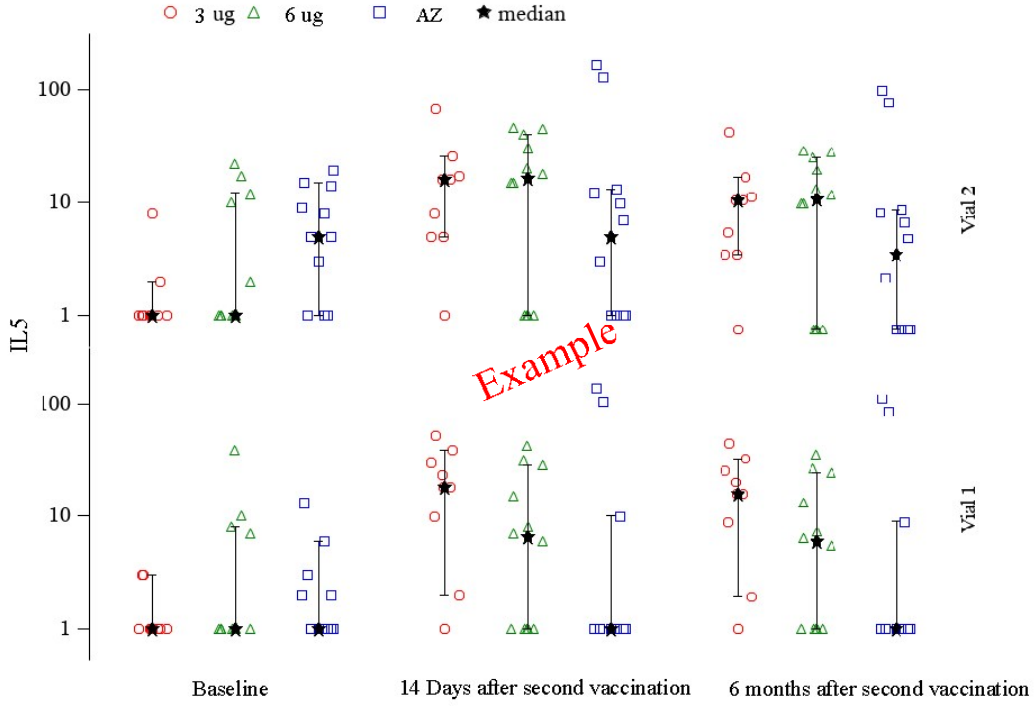
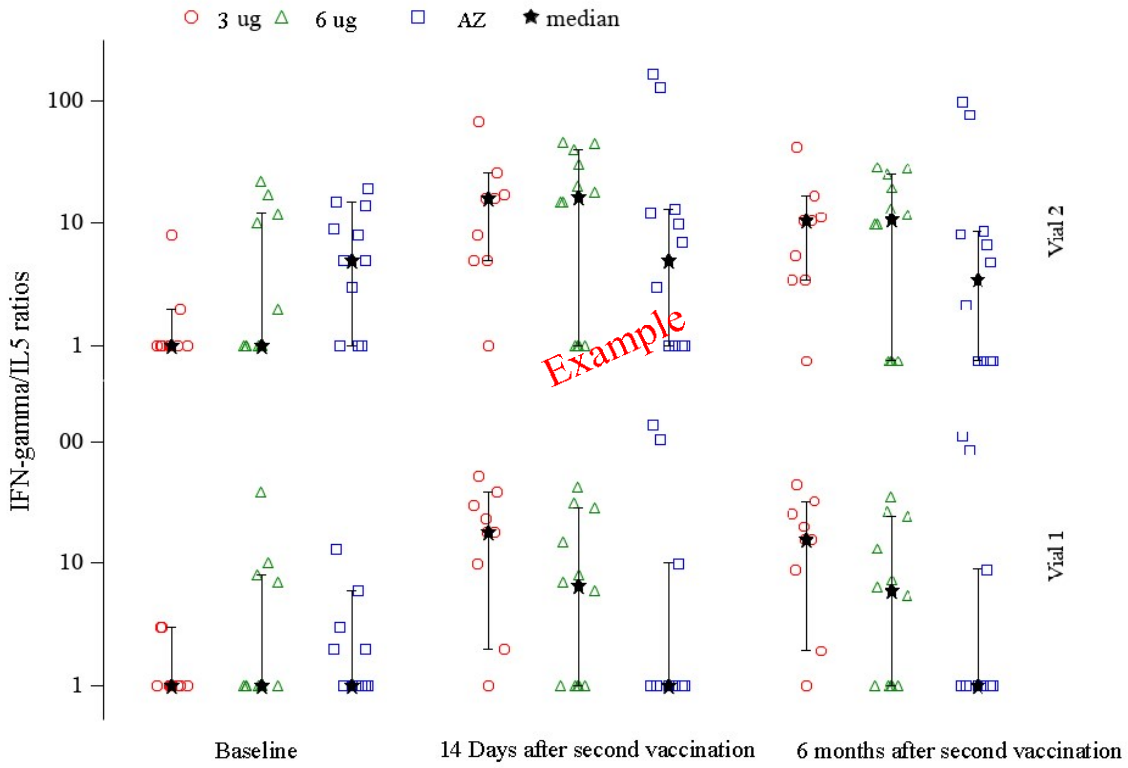


**Figure 23: IFN- gamma/IL5 Ratios, Median and 95% Confidence Interval by Vial, Follow up Visit and Vaccination Groups in Per Protocol Analysis Population**



# APPENDIX 3. LISTINGS

## LIST OF LISTINGS

## Listing 1: Reasons of Incomplete Study

| Subject ID | Reason | Vaccination Group |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

## Listing 2: Subject Specific Protocol Deviation

| Subject ID | Reason for Deviation | Vaccination Group |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

## Listing 3: Demographics

| Subject ID | Vaccination Group | Sex | Age (years) | Height (cm) | Weight (kg) | BMI | Race |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

## Listing 4: Medical History

| Subject ID | Vaccination Group | Diagnosis | Past/Current | System Organ Class (SOC) | Preferred Term (PT) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

## Listing 5: Concomitant Medications

| Subject ID | Vaccination Group | Medication | Medication Start Date | Medication End Date/ Ongoing | Indication (MH, PIR, AE) | Anatomical Main Group | Therapeutic Subgroup |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

## Listing 6: Solicited Local and Systemic Reactions with Severity Grade

| Subject ID | Vaccination Group | After Dose (1st/2nd) | Reaction | Follow-up Time Point* | Severity Grade |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

* Follow-up time point: 30 minutes or 7 days after vaccination

## Listing 7: Unsolicited Adverse Events

| Subject ID | Vaccination Group | Vaccination Date | AE# | Verbatim Term | System Organ Class (SOC) | Preferred Term (PT) | Start Date | End Date/ Ongoing | Serious? (Y/N) | MAAE? | AESI? | Severity | Outcome | Relationship to study vaccine | Action taken to study vaccine |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

## Listing 8: Serious Adverse Events

| Subject ID | Vaccination Group | Vaccination Date | AE# | Verbatim Term | System Organ Class (SOC) | Preferred Term (PT) | Start Date | End Date/ Ongoing | MAAE? | AESI? | Severity | Outcome | Relationship to study vaccine | Action taken to study vaccine |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |

## Listing 9: Vital Sign Results

| Subject ID | Vaccination Group | Parameter | Visit | Value | Change from Baseline |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

## Listing 10: Physical Examination Results

| Subject ID | Vaccination Group | Parameter | Visit | Normality (Normal/ Abnormal/ Not done) | If abnormal, clinically significant (Yes/No) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

## Listing 11: NT50 against SARS-CoV-2 Pseudovirus

| Subject ID | Vaccination Group | Visit | NT50 (IU/mL) |
|---|---|---|---|
| | | | |
| | | | |

## Listing 12: Anti-S IgG Titers assessed by ELISA

| Subject ID | Vaccination Group | Visit | Anti-S IgG titer (BAU/mL) |
|---|---|---|---|
| | | | |
| | | | |

## Listing 13: S protein-specific T cell by ELISPOT

| Subject ID | Vaccination Group | Visit | IFN-gamma (ELISpot SFU/1x$10^6$ cells) | IL5 (ELISpot SFU/1x$10^6$ cells) |
|---|---|---|---|---|
| | | | | |
| | | | | |