STATISTICAL ANALYSIS PLAN

Version 2.0 dated 29-05-2023

A Multi-Centre, Randomized, Double Blind, Phase 2b Trial to Evaluate the Safety and Immunogenicity of Janssen Ad26COVS1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) and Novavax NVX-CoV2373 COVID-19 vaccines for Homologous and Heterologous Boosting in Adolescents and Adults Aged 12 to 64 Years with and without HIV infection in 3 African Countries (Kenya, Democratic Republic of Congo, and Rwanda).

Study Principal Investigators:
Lucas Otieno Tina, MD MPH, Victoria Biomedical Research Institute, Kenya
Amos Ndhere, MD MS, Victoria Biomedical Research Institute, Kenya

Collaborating Country Principal Investigators:
Hypolite Muhindo, MD PhD, University of Kinshasa, Democratic Republic of Congo
Vincent Mutabazi, MD MSc, Rinda Ubuzima & University of Rwanda, Rwanda

Sponsor: Victoria Biomedical Research Institute
P.O. Box 7180, Postal Code 40100,
Kisumu, Kenya
Tel: +254 720 597654
Website: https://www.vibriafrica.org

Funded by: Coalition for Epidemic Preparedness Innovation

Based on protocol #: VIBRI COVID-19-001/2021, Version: 3.0

Prepared by:

ACE Research

Table of Contents

1. Introduction

1.1. Study summary

The Victoria Biomedical Research Institute (VIBRI) is leading a Multi-Centre Phase 2b RCT to evaluate the Safety and Immunogenicity of the Janssen Ad26COVS1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) and the Novavax NVX-CoV2373 used as homologous and heterologous boost strategies among HIV positive adolescents and adults with a small control arm of HIV (-) participants. The trial aims to enrol about 300 adolescents and 1,650 adults aged 12 to 64 years, who have completed one of the primary vaccine series with a homologous vaccine based on (a) mRNA (Moderna or Pfizer), (b) adenovirus 26 (J&J) or (c) inactivated (Sinopharm). These three have been the main vaccine platforms introduced across the three participating countries (Kenya, Democratic Republic of Congo and Rwanda). In total, the study will enrol 1950 participants into the vaccination cohort with HIV (+) adults to comprise 1350 (2:1 strata of ages 18-44 and 45-64, respectively), HIV (+) adolescents (ages 12-17) to comprise 300 and HIV (-) adults (ages 18-44) to comprise 300. The protocol (# VIBRI COVID-19-001/2021, version 3.0 and dated 16th January 2023) provides detailed information about the proposed study.

1.2. Study objectives, endpoints, and timepoints

The study proposes to address the primary, secondary, and exploratory objectives (matched with the corresponding endpoints and timepoints) summarised in **Table 1**.

Table 1: Summary of objectives, endpoints, and timepoints (after vaccine boost) [1]

Objective	Endpoint (s)	Timepoint (s)
1.2.1. Primary		
• To evaluate reactogenicity (solicited adverse events (AEs) Ad26.COV2S1 and NVX-CoV2373 for adults or NVX-CoV2373 vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccine for adolescents following boosting.	• Occurrence of solicited AEs (local and systemic) reactogenicity events through 7 days following boosting vaccination. Analysis to include by HIV status, age group, booster treatment group, and heterologous vaccination series (primary platform + boosted vaccine).	• Day 0 to 7
• To evaluate Serious Adverse Events (SAE) related to vaccination of Ad26.COV2S1 or NVX-CoV2373 for adults or NVX-CoV2373 vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccine for adolescents during the entire study.	• Incidence of vaccine related Serious Adverse Events (SAEs) throughout the study period. Analysis to include by HIV status, age group, booster treatment group, and heterologous vaccination series (primary platform + boosted vaccine).	• Day 0 to Month 18
• To evaluate the immunogenicity of Ad26.COV2S1 and NVX-CoV2373 vaccines for adults or NVX-CoV2373 vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccine for adolescents at day 28	• SARS-CoV-2 neutralization: SARS-CoV-2 neutralizing titers in serum measured by a virus neutralization assay (VNA) using pseudovirion expressing S protein (standardized to 50% neutralization with 95% CI). • Serum IgG antibodies to SARS-CoV-2 rS protein measured by enzyme-linked immunosorbent assay (ELISA) using geometric mean titers (GMT with 95% CI). • Geometric mean fold ratio over baseline. Analysis to include by HIV status and booster treatment group (Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2372).	• Day 28
1.2.2. Secondary		
• To evaluate all unsolicited AEs post-vaccination through 28 days and treatment emergent adverse events through 85 days in all participants.	• Incidence of unsolicited AEs by MedDRA coding (high ordered term and preferred term), severity and relatedness. Analysis to include by HIV status, age group, booster treatment group, and heterologous vaccination series (primary platform + boosted vaccine).	• Day 0 to EOS
• To evaluate safety in terms of adverse events of special interest (AESIs) following vaccination, for HIV (+) participants through end of study.	• Incidence of AESIs for all participants following vaccination throughout Day 85 and for HIV (+) participants through the EOS. AESI will be assessed as Potential Immune- Mediated Diseases (pIMDs), associated with COVID-19 infection, or any events deemed of special interest by any COVID-19 vaccines received during boosting. • In the case of confirmed COVID-19 cases, classification as asymptomatic, mild, moderate or severe along with analysis of symptoms, signs post diagnosis (self-reported). Time to symptom resolution and time to negative Ag test will be derived. For participants with moderate or severe symptoms genetic typing of SARS-CoV2 will be reported. Analysis to include age group, booster treatment group, and heterologous vaccination series (primary platform + boosted vaccine).	• Day 0 to EOS
• To describe severe adverse events through end of study in all participants.	• Analysis to include by HIV status, age group, booster treatment group, and heterologous vaccination series (primary platform + boosted vaccine).	• Day 0 to EOS

[1] There is currently no public information on safety and immunogenicity of the Janssen Covid-19 vaccine in adolescent/paediatric populations. As a result, the recommendation for use of the Janssen Covid-19 vaccine for primary or booster vaccination in adolescents/paediatric populations has not yet been made public. Therefore, this study evaluates: (i) Janssen Ad26COVS1 and Novavax NVX-CoV2373 for HIV+ and HIV- participants aged 18 – 64 years; and (ii) mRNA (Moderna mRNA-1273 or Pfizer/BNT) and Novavax NVX-CoV2373 vaccines for HIV+ adolescents.

• To compare the immunogenicity of heterologous boost in participants at Day 28 (IgG ELISA and neutralization)	• Means and 95% CI for VNA, GMT, geometric mean fold rise (GMFR) from baseline to Day 28. Analysis to include by HIV status, age group, treatment group, and heterologous vaccination series (primary platform + boosted vaccine).	• Day 0 and Day 28
• To compare the durability of response through end of study (IgG ELISA and neutralization)	• Mean and 95% CI for VNA, GMT, geometric mean fold rise (GMFR). Analysis to include by HIV status, age group, treatment group, and heterologous vaccination series (primary platform + boosted vaccine).	• Day 0 to EOS
• To evaluate mucosal immunogenicity of heterologous boost in participants at Day 28 (S-IgA ELISA).	• Mucosal secretory (S-IgA) to SARS-CoV-2 rS protein measured by enzyme-linked immunosorbent assay (ELISA) using geometric mean titers (GMT) and GMFR at Day 28. Analysis to include by HIV status, age group, treatment group, and heterologous vaccination series (primary platform + boosted vaccine).	• Day 0 and Day 28
1.2.3. Exploratory		
• To evaluate the occurrence SARS-CoV-2 infection and level of severity in participants	• Incidence of rapid antigen and virologically confirmed SARS-CoV-2 starting at Day 28 through EOS in all participants, by subject reported symptomatology, duration and severity. Classification as asymptomatic, mild, moderate or severe along with analysis of symptomatology (type/duration) and time to symptom resolution and time to negative rapid Ag test will be derived. Analysis to include HIV status, age group, booster treatment group, and vaccination platform/series.	• Day 28 to EOS
• To evaluate the occurrence SARS-CoV-2 variants of concern in all participants with moderate to severe disease following boosting vaccination.	• Incidence of virologically confirmed SARS-CoV-2 variants of concern (e.g., B.1.351, B.1.1.7, B.1.617, B.1.1.529, or others to be identified as the pandemic evolves)-COVID-19, starting at Day 28 through EOS in participants who develop moderate or severe COVID-19 disease. Analysis to include HIV status, age group, booster treatment group, vaccination platform/series and SARS-CoV-2 severity grade.	• Day 28 to EOS
• To evaluate the Cell Mediated Immune response of Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) and NVX-CoV2372 vaccines in adults HIV (+) and HIV (-) participants	• SARS-CoV-2 Cell Mediated Immunity in Peripheral Mononuclear Cells (PBMCs) as measured by ELISPOT on Day 7 following boost. Analysis to include boost treatment group and heterologous vaccination series (primary platform + boosted vaccine).	• Day 7
• To identify a threshold of immune protection for HIV (+) and HIV (-) participants to prevent SARS-CoV-2 following vaccination.	• Analysis of breakthrough cases with GMT and VNA levels to determine a potential threshold of protection (through EOS).	• Day 28
• To assess if changes in control of HIV infection (by viral loads and CD4 counts) has an effect on immune responses or breakthrough SARS-CoV-2 infection rates/severity during the trial.	• Assessment of changes in viral loads and CD4 counts during long term immune durability within HIV subjects (by booster and by primary vaccination platform).	• Months 6,12 and 15-18

1.3. Purpose and scope of the plan

Statistical approaches that would be used to address the primary, secondary, and exploratory objectives stated in section 1.2 were broadly highlighted in the protocol. This Statistical Analysis Plan (SAP) therefore provides more detailed information on the proposed statistical approaches and procedures that will be used to analyse the data collected in the research study. In addition, sample tables, listings and figures planned for the interim and final analyses are provided.

2. Design

2.1. Study design

A multi-site, multi-stage randomized, double-blind Phase 2b trial with 3 arms and a follow up period of 12-18 months.

2.2. Study population

The target population for this Phase 2b study is HIV+ adolescents ≥ 12 to 17 years and HIV (+) and HIV (-) adults aged ≥ 18 to 64 years. Participants will be screened for eligibility criteria at the time of inclusion and may be enrolled anytime from 3-7 months of completing their primary homologous vaccination series for adults and 3 – 12 months following completion of primary series for adolescents. Randomization will occur on day of vaccination and participants should have completed the primary vaccine series in the last 5 to 7 months for adults and 5 to 12 months for adolescents. Randomization will be 1:1 to either the Janssen (or mRNA (Moderna mRNA-1273 or Pfizer/BNT)) vaccine or Novavax vaccine within each primary vaccine platform. The duration of each participant's participation in the trial will be approximately 15-18 months for adults depending on time of enrolment relative to boosting (subjects will be followed through for at least 15 months post boost). Adolescents follow up will be upto 12 months. Adherence to inclusion and exclusion criteria (see the latest version of the protocol version 3.0 for details), is essential to ensure safety to participants and precise comparison of groups. Waivers on inclusion and exclusion criteria are not allowed because they could jeopardize the scientific integrity of the study, regulatory acceptability, or participant safety.

2.3. Sample size

Sample size estimation was based on the following primary objectives:

- To evaluate reactogenicity (solicited adverse events (AEs) Ad26.COV2S1 and NVX-CoV2373 for adults or for adults or NVX-CoV2373 vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccine for adolescents following boosting.
- To evaluate Serious Adverse Events related to vaccination of Ad26.COV2S1 or NVX-CoV2373 for adults or NVX-CoV2373 vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccine for adolescents during the entire study.
- To evaluate the immunogenicity of Ad26.COV2S1 and NVX-CoV2373 vaccines for adults or NVX-CoV2373 vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccine for adolescents at day 28.

To address these three main objectives, the study will enrol both HIV+ and HIV- participants, with a greater proportion of HIV+ individuals. Hence, for calculating the sample size, we used the formula described by Wittes (2002), which considers the imbalance in participant distribution between the two groups[2]. We further considered the following assumptions and conditions:

- The expected incidence of solicited and serious adverse events (AEs) in HIV+ would be approximately 60% and 10% respectively.
- The expected Geometric Mean of IgG would be at least 1000 IU/ml (with a standard deviation of 500).
  NOTE: These estimates were derived from a recent meta-analysis by McDonald (2021) which evaluated the difference in AEs between vaccinated individuals and various control groups[3].
- We anticipate little to no variation in AEs across the sites, hence there was no need to adjust the sample size by a design effect.
- We varied effect sizes – risk ratios for (Serious) Adverse Events and absolute mean geometric differences for immunogenicity.
- Considered a ratio of 4.5:1 for HIV+ and HIV- participants.
- Assumed HIV- participants would act as potential controls.

Based on these assumptions, we assessed the effect sizes that could be feasibly detected at a power of 80% and 90% and a significance level of 5% for each objective. The findings are presented in **Figure 1**. Using a sample size of approximately 1950, the expected plausible and detectable risk ratio for solicited and serious AEs in HIV+ participants (compared to HIV-

[2] https://pubmed.ncbi.nlm.nih.gov/12119854/
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8116645/

participants) would be around 1.2 and 1.8, respectively. Similarly, the same sample size would enable the detection of a difference of roughly 600 IgG in geometric mean.

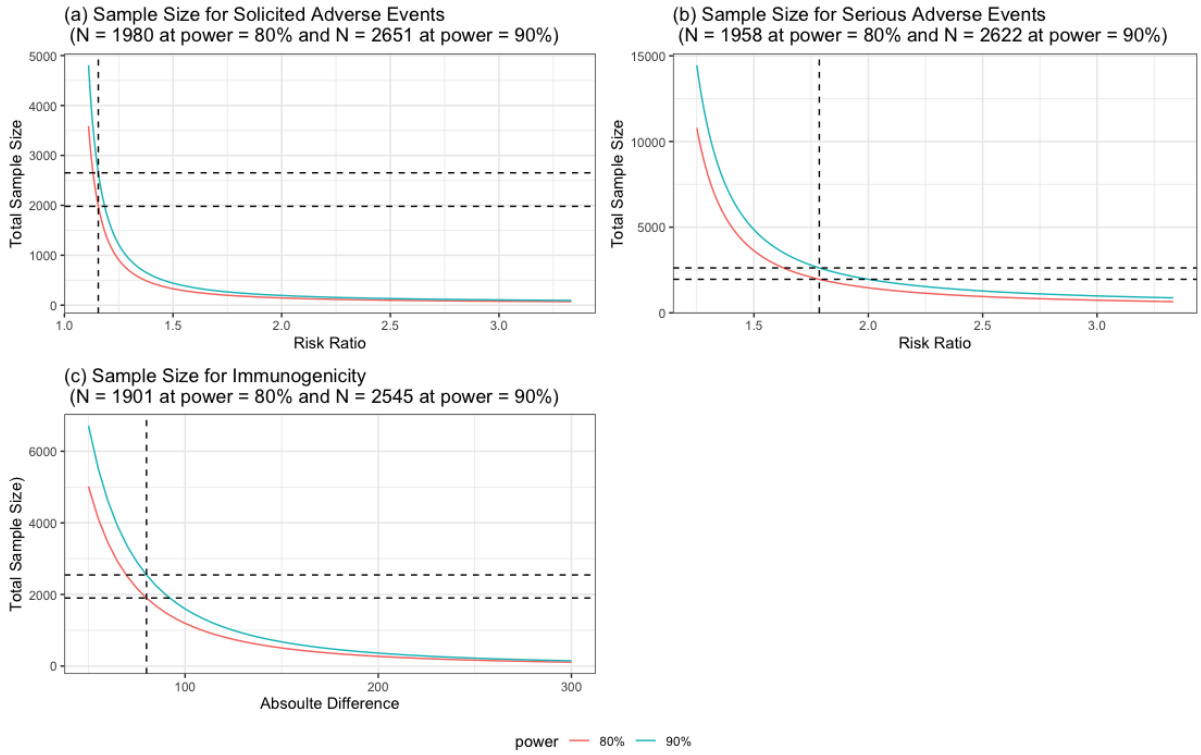


Figure 1: Sample sizes for determining differences in reactogenicity and immunogenicity outcomes.

A minimum sample size of 1950 was therefore considered sufficient to answer all the three primary objectives. Of which 1350 would be HIV (+) adults (450 participants in each primary platform), 300 HIV (-) adults (450 participants in each primary platform) and 300 HIV (+) adolescents (150 in the mRNA platform and 150 in either the Adeno26 or inactivated whole virus or both platforms). See **Table 2 a and b** for detailed distribution by vaccine platform, HIV status, age category, and vaccine treatment arm.

Table 2a: Study Design-Homologous and Heterologous Prime-Boost Vaccination Adult Groups

Vaccine Platform for Primary Series	HIV (+) adults (age 18-64)	HIV (-) Adults (age 18-64)	Booster vaccination (5-7 months) 1:1*
mRNA (Moderna mRNA-1273 or Pfizer/BNT)	450	100	Janssen Ad26COVS1
			Novavax NVX-CoV2373
Adenovector 26 (Janssen Ad26COVS1)	450	100	Janssen Ad26COVS1
			Novavax NVX-CoV2373
			Janssen Ad26COVS1

Inactivated whole virus (Sinopharm-BIBP or Sinovac)	450	100	Novavax NVX-CoV2373
Total	**1,350**	**300**	**Maximum 1,950**

*Booster vaccination for adolescents will be ≥5-12 months after the last primary vaccination series.

Table 2b: Study Design-Homologous and Heterologous Prime-Boost Vaccination Adolescent Groups

Vaccine Platform for Primary Series	**HIV (+) adolescents (age 12-17)**	**Booster vaccination (5-12 months) 1:1**
mRNA (Moderna mRNA-1273 or Pfizer/BNT)	150	Novavax NVX-CoV2373
	150	Moderna mRNA-1273 or Pfizer/BNT**
Total	**Maximum 300**	**Maximum 300**

** Monovalent or bivalent vaccines depending on MOH availability and supply.

2.4. Study schema

The trial will assess the safety, and immunogenicity of Janssen Ad.26COV2.S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) and Novavax NVX-CoV2373 booster vaccines in adults 18-64 years of age and adolescents 12-17 years of age in 2 stages. In Stage 1, the booster vaccines will be evaluated in adult participants 18-64 years while in Stage 2, the booster vaccines will be assessed in adolescents 12-17 years of age. **Figures 2 and 3** provide schematic overview of these two stages – highlighting vaccine platforms, study population, follow up time, and allocated sample sizes.

Figure 2: Study Schematic Overview: Stage 1: 1,350 Adults HIV (+) Age 18-64 years old & 300 Adults HIV (-) Age 18-44 years old

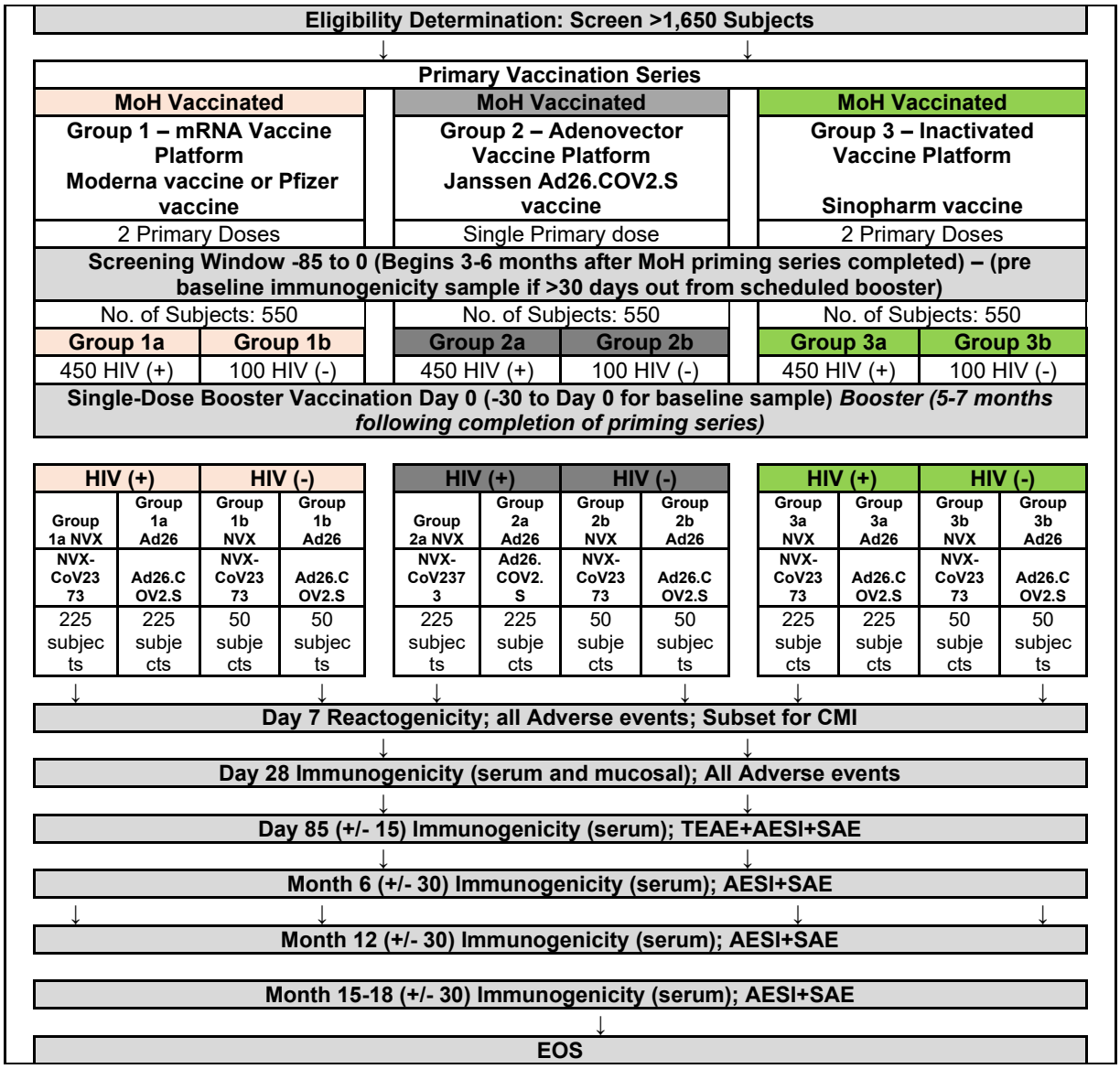
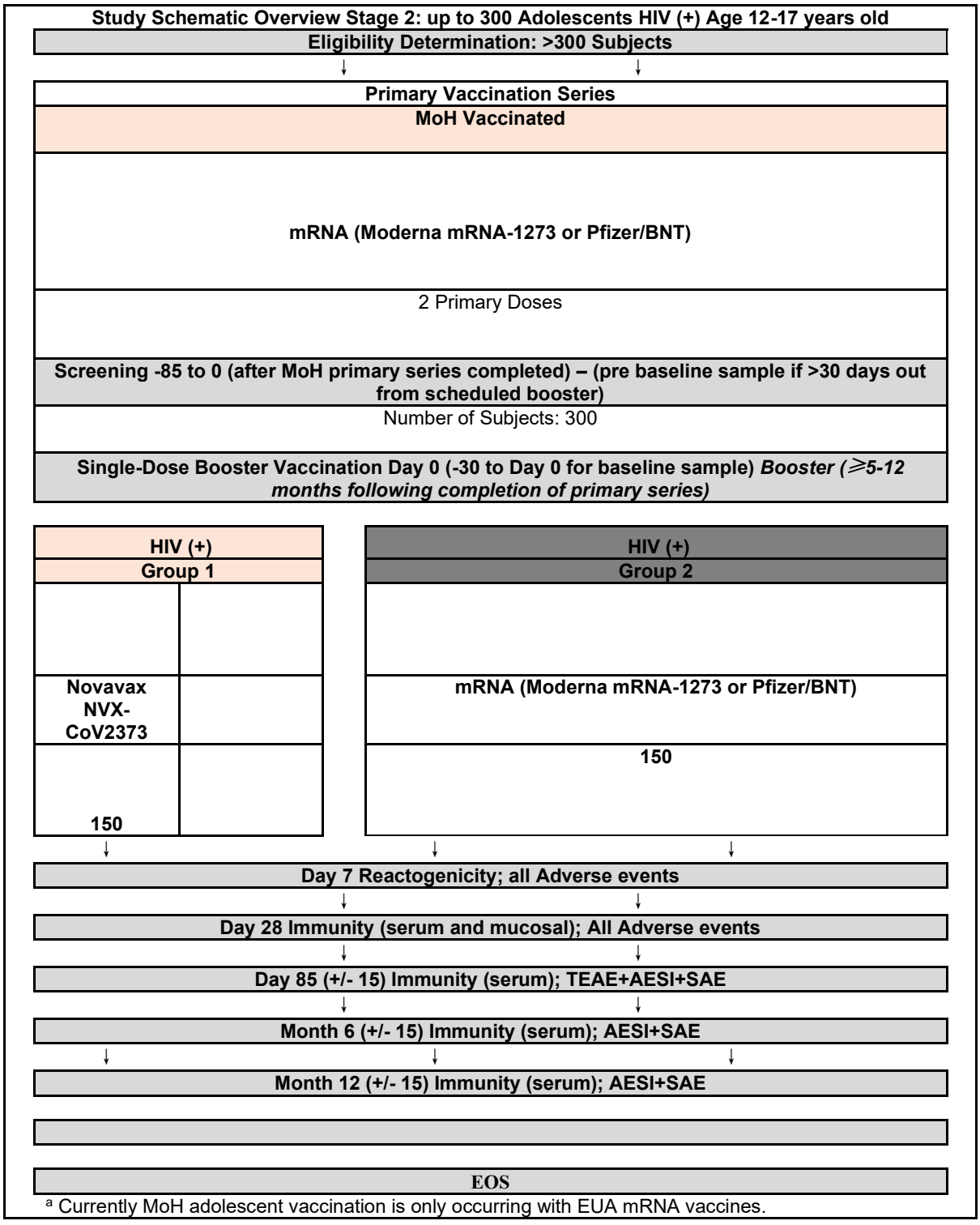


Figure 3: Study Schematic Overview: Stage 2: 300 Adolescents HIV (+) Age 12 – 17 years old



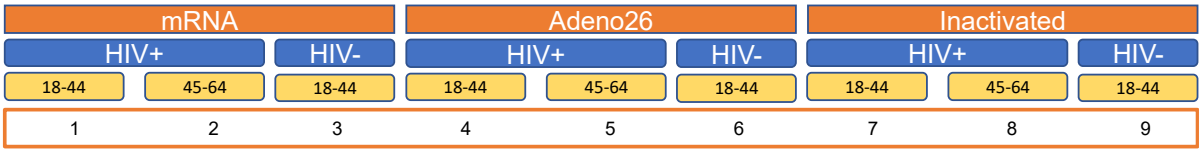
[a] Currently MoH adolescent vaccination is only occurring with EUA mRNA vaccines.

2.5. Randomisation

We highlight the randomisation approach for **stage 1** (for recruitment of adults) and **stage 2** (for recruitment of adolescents). As the sample size goals are: (i) 2:1:1 for Kenya, DRC and Rwanda, (ii) 1:1:1 for mRNA (Moderna or Pfizer), adenovirus 26 (J&J) and inactivated (Sinopharm) platforms, (ii) 2:1 for 18-45, 46-64 HIV+ participants, and 4.5:1 for HIV+ and HIV-

participants, we stratified the allocation by country, vaccine platform, HIV status and age category. This resulted in nine strata for adults per country as shown in **Figure 4**. We note that HIV+ adolescents had only one stratum. Therefore, in total, randomisation in this evaluation examined 10 strata.

Figure 4 a: Strata layout for recruitment of adults aged 18 – 64 years



A sequence of random permuted blocks of varying sizes were then applied to each stratum to ensure a 1:1 allocation ratio to receive either the Novavax NVX-CoV2373 vs Janssen Ad26COVS1 vaccine for adults or Novavax NVX-CoV2373 vs mRNA for adolescents. These blocks, and the subsequent assignment codes were generated using the *ralloc* command for allocation of treatments using random permuted blocks in STATA version 17 [1]. **Table 5** shows expected distribution of adults based on expected ratios. While the expected allocation of adolescents between NVX-CoV2373 and mRNA vaccines would be 150 individuals on each vaccine arm.

Table 5: Expected distribution of adults (18 – 64 years) by vaccine arm stratified by country and each of the nine strata.

	Strata									**Total**
	mRNA			Adeno26			Inactivated			
	HIV+	HIV+	HIV-	HIV+	HIV+	HIV-	HIV+	HIV+	HIV-	
	18-44	45-64	18-44	18-44	45-64	18-44	18-44	45-64	18-44	
Rwanda										
NVX	34	18	16	34	18	17	35	18	17	207
Ad26	34	18	16	34	18	17	35	18	17	207
Total	**68**	**36**	**32**	**68**	**36**	**34**	**70**	**36**	**34**	**414**
DRC										
NVX	34	18	16	34	18	17	35	18	17	207
Ad26	34	18	16	34	18	17	35	18	17	207
Total	**68**	**36**	**32**	**68**	**36**	**34**	**70**	**36**	**34**	**414**
Kenya										
NVX	80	41	18	80	40	17	80	40	17	413
Ad26	80	41	18	80	40	17	80	40	17	413
Total	**160**	**82**	**36**	**160**	**80**	**34**	**160**	**80**	**34**	**826**

Information regarding the randomization plan had been shared with the data management team for integration into the data capture system.

2.6. Blinding and unblinding

This is a double-blind study whereby blinding will not be broken until the end of the study unless it is warranted by the safety concerns and medical treatment of a participant. Randomization codes will be maintained within the IRT/iWRS to allow the investigator to break

the blind for an individual participant as need arises. If a subject is unblinded during the study, it is to be reported as a protocol deviation except in the event of a medical emergency or a Suspected Unexpected Serious Adverse Reaction (SUSAR) to determine regulatory reporting. Subsequent actions after breaking the blind are documented in the protocol in section 6.3.1.2.

2.7. Interim Analysis

A total of three (3) interim analyses shall be conducted:

(i) Safety and immunogenicity (primary endpoint) analysis following day 28 visit.

(ii) 6 months after the study booster vaccines are administered and

(iii) 12 months after booster vaccines are given to the participants.

The interim analyses shall be conducted at treatment platform level only. After completion of the long term follow up (15 to 18 months) for adults and 12 months for adolescent group, a database lock shall be implemented.

2.8. Analysis sets

We highlight in **Table 6** the planned analysis sets with the corresponding populations that would be included in each.

Table 4: Planned analysis sets

Analysis Set	Description
Safety analysis set	Will consist of all randomised participants who receive at least one dose of the study vaccine.
Intent-to-treat analysis set	Will consist of all randomised participants classified by the study group.
Immunogenicity analysis set	Will consist of all participants in the intent-to-treat analysis set who receive study vaccine, have a baseline and at least 1 post-vaccination sample for which valid results were reported for the test being analysed, and did not receive any COVID-19 vaccine or monoclonal antibody outside of the study. This set will also be referred to as the Full analysis set (FAS).

3. Statistical Methodology

We first present the general principles that will apply across the proposed analyses before detailing the statistical approaches that will be used to answer each of the study objectives.

3.1. General Principles

Results of descriptive analysis will be disaggregated by HIV status, age group, booster treatment group, and heterologous vaccination series (primary platform + boosted vaccine). In addition to these stratification variables, medical history and adverse events will be presented by MedDRA System organ class (SOC) and preferred terms (PT).

All continuous variables will be summarised using the following descriptive statistics as appropriate: n (non-missing sample size), mean, standard deviation, median, maximum and minimum. Skewed continuous variables will be summarised using medians/geometric mean (where appropriate), inter-quartile ranges and range values, and number of missing values.

The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures.

All summary tables for adults (18 – 64 years) will be structured with a column for each of the 3 primary platforms (in the order mRNA, Adeno26, inactivated) and will be annotated with the total population size relevant to that table/primary platform. While the summary tables for adolescents will have two columns for mRNA and Novavax booster vaccine assignments.

Immunogenicity data below the lower limit of detection/ quantification will be imputed by a value half of the lower limit of detection, prior to any transformation. Data above the high limit of detection/quantification shall be reviewed by the study immunologist before any imputation is done. The distribution of antibody titers are generally skewed [2]. Therefore, prior to any statistical analysis that assumes normally distributed observations, antibody titters will be transformed using the natural log.

In all analysis where adjustments shall be made for multiple comparisons, the Holm-Bonferroni method shall be used. This correction method, is preferred over the traditional Bonferroni's correction which is too conservative and prone to incur false negative results [3].

The analysis will be done for each individual country as well as in aggregate.

3.2. Descriptive analysis of study Population

This sub-section highlights the descriptive analysis approaches that will be conducted on the baseline and demographic characteristics of the study participants. In addition, analysis approaches on the recruitment outcomes of the participants are also presented.

3.2.1. Disposition of Subjects and Withdrawals

All subjects who provide informed consent will be accounted for in this study. The frequencies and percentages of subjects in each analysis set, study withdrawals, subgroups, and major protocol deviations will also be presented. The time the subjects are under observation will be summarized using summary statistics (mean, SD, minimum, median, maximum). Proposed

outlines of tables that will show these results are presented in the appendix (Table 7.1, *Table 7.2*, Table 7.3**,** Table 7.4**,** Table 7.8 1 to Table 7.8 3**)**

3.2.2. Protocol Deviations

A summary of subject-specific protocol deviations will be presented by the number and percentage of subjects with a specific protocol deviation (*Table 7.5*). All reportable protocol deviations will be evaluated before unblinding and classified according to International Conference on Harmonisation (ICH) into the categories highlighted in **Table 7**:

Table 7: Classification of protocol deviations according to ICH

Protocol deviation	Category
1. Subject developed withdrawal criteria during the study but was not withdrawn	• Underlying medical condition forbidden by the protocol or which may influence immune response. • Subject had contraindication for a subsequent study vaccination but was vaccinated. • Concomitant infection related to the vaccine which may influence immune response.
2. Subject received wrong vaccine or incorrect dose	• Study vaccine was not administered at all • Vaccine administration not according to protocol. • Randomization failure.
3. Subject took an excluded concomitant medication	• Administration of concomitant vaccine(s) forbidden in the protocol. • Administration of any medication forbidden by the protocol.
4. Subject randomized and did not satisfy the entry criteria.	• Subject did not meet entry criteria.
5. Key study procedures missed or performed out of window	• Randomization code was broken. • Subject did not comply with study vaccination schedule. • Subject did not provide any post-vaccination safety data. • Subject did not comply with blood draw schedule. • Serological results not available post-vaccination. • Obvious incoherence or error in data.

3.2.3. Demographic and Other Baseline Characteristics

Age, height, weight, body mass index will be summarized by reporting the mean, standard deviation, median and range. The frequencies and percentages of subjects by sex, ethnic origin, race, entry criteria fulfilled will also be presented (*Table 7.6 1* to *Table 7.6 3*). Medical history data will be tabulated for the all-enrolled Set (*Table 7.7.1* to *Table 7.7. 6*).

3.2.4. Previous and concomitant Medications

A previous medication refers to the medications that participants have prior to the their first study vaccination (i.e. medication end date < first study vaccination date). It includes information about any prescription medications, over-the-counter drugs, herbal supplements, or other treatments they have used in the past. All other medications are concomitant. Concomitant Medications are the medications that participants are currently taking or begin using during the course of the clinical trial. When start and/or end dates of a medication intake are missing, the medication is considered as concomitant with the study vaccination schedule. If the first study vaccination date is missing then the medication is considered as concomitant with the study vaccination schedule, provided that the study vaccine was administered to the subject.

3.3. Primary Analysis

3.3.1. Solicited Adverse Events (AEs)

Solicited AEs will be recorded in the study database for 7 days after administration of the study booster vaccines. Study participants will be given a diary card to use as a memory aid, on which to record the solicited signs and symptoms daily until the return to clinic day (day 7). Reported AEs shall be assigned an FDA toxicity grade to each event as presented in **Table 8** below.

Table 8: FDA toxicity grading of AEs

Grade	Description	Impact of events
0	No AE	
1	Mild	Events require minimal or no treatment and do not interfere with the participant's daily activities.
2	Moderate	Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
3	Severe	Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious”.

These AEs shall be summarised as the number and percentage of participants with AEs. The occurrence of solicited AEs will be reported using the number and proportion of subjects reporting at least one solicited AE. To evaluate the occurrence of solicited AEs, the following hypotheses shall be tested:

> **H0 (Safety):** There is no expected difference in % solicited adverse events (AEs) across the three vaccine platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.
> **H1 (Safety):** There is an expected difference in % solicited adverse events (AEs) across the three vaccine platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

Presence of AEs shall be coded as a binary outcome (Yes / No) and a contingency table used to present this outcome based on the booster vaccine received. The chi square exact test shall be used to investigate if there is no difference in the proportion of study participants with or without AEs between the two study booster vaccine groups (Table 7.15. 1 to *Table 7.15. 6*). Should the assumption of the chi-square test be violated (i.e., count of <5 participants in a cell in the contingency table) then the Fishers exact test shall be used. In addition, the log binomial model shall be used to estimate the risk ratio of AE occurrence between the booster vaccines. The model will adjust for stratification variables highlighted under the general principles. This analysis will be considered when there is a sufficiently high rate of solicited AEs.

3.3.2. Serious Adverse Events

To investigate the occurrence of Serious Adverse Events (SAEs), the following hypothesis will be examined:

H0 (Safety): There is no expected difference in SAE rate attributed to vaccine across the three vaccine platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

H1 (Safety): There is an expected difference in SAE rate attributed to vaccine across the three vaccine platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

Of interest will be the number and proportion of individuals with at least one AE as well as the number of AEs. Depending on the proportions of participants with SAEs, log binomial regression will be used to estimate the risk ratios (RR) while adjusting for the stratification variables.

In conclusion, the following outputs will be produced to provide summary statistics for the primary analysis section 3.3:

i. Subject level summary of reported or clinically observed symptoms following administration of study booster vaccine (Listing 8.1.1).

ii. Subject incidence of AEs (

	mRNA		Adeno26		Inactivated whole virus	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novava
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Systolic blood pressure						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Diastolic blood pressure						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Pulse/ Heart rate						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Pulse/ Heart rate						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Respiratory Rate						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Temperature						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

iii. Table 7.9. *1* Table 7.7.*1* to

iv. *Table 7.9. 6*,

v. *Table 7.10. 1* to Table 7.10. 6, *Table 7.11. 1* to Table 7.11. 6, *Table 7.12. 1* to Table 7.12. 6, Table 7.13. 1 to Table 7.13. 6 and 7.14.1-7.14.6).

vi. Total frequency AEs (

	mRNA		Adeno26		Inactivated whole virus	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novava
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Systolic blood pressure						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Diastolic blood pressure						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Pulse/ Heart rate						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Pulse/ Heart rate						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Respiratory Rate						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Temperature						
N	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

vii. Table 7.9. *1* Table 7.7.*1* to

viii. *Table 7.9. 6*,

ix. *Table 7.10. 1* to Table 7.10. 6, *Table 7.11. 1* to Table 7.11. 6, *Table 7.12. 1* to Table 7.12. 6, Table 7.13. 1 to Table 7.13. 6 and 7.14.1-7.14.6).
x. Subject listing of unsolicited AEs by MedDRA classification (Listing 8.1.2)
xi. Bar chart of non-serious AEs by severity and MedDRA SOC
xii. Bar chart of non-serious AEs by severity
xiii. Bar chart of non-serious AEs by relationship to study vaccines and MedDRA SOC
xiv. Bar chart of non-serious AEs by relationship to study vaccines

3.3.3. Immunogenicity Analysis

To evaluate the immune response of the study participants, the following hypotheses shall be tested:

(i) **H0 (Immune Response IgG):** There is no expected difference in the Geometric Mean Titres (GMT) or Geometric Mean Fold Rises (GMFR) response by ELISA between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

H1 (Immune Response IgG): There is an expected difference in the GMT or GMFR response by ELISA between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

(ii) **H0 (Immune Response Neutralization):** There is no expected difference in the neutralization titre response (absolute or GMFR) between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

H1 (Immune Response Neutralization): There is an expected difference in the GMT response by neutralization titre response (absolute or GMFR) between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

(iii) **H0 (Immune Responses compared to immune competent):** There is an expected lower immune response over time (IgG ELISA and neutralization titres) for any one platform or across all platforms after boosting with either

Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

H1 (Immune Responses compared to immune competent): There is expected immune response over time (IgG ELISA and neutralization titres) for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

Blood samples to evaluate immunogenicity will be drawn at baseline (day 0) and at specified time points in the protocol (days 28, 85 and months 6, 12 and 18). The primary immunogenicity endpoint is 28 days after the second injection. Measurements of SARS-CoV-2 specific immune responses will be assessed by virus neutralization assay (VNA) and serum IgG antibodies. A high variation of the VNA and IgG antibody titers is expected. In addition, it is assumed that log-transformed values are normally distributed; therefore, values will be logarithmically transformed (natural log) and all statistical analyses on antibody levels will be performed on the logarithmic scale. However, should the natural log transformation fail to attain normality, other distributions such as the log normal, Gamma, Inverse Gaussian shall be applied and model fit examined appropriately.

To evaluate immunogenicity, the mean and 95% CI of the VNA and IgG antibody titters will be generated and presented as:

i. GMT and their confidence intervals
ii. Geometric mean ratio (GMR) of results obtained at baseline to results obtained at follow-up visits and 95% CI
iii. Geometric mean fold ratio (GMR) of results obtained at baseline (Randomization) to results obtained at day 28 and its 95% CI.
iv. Boxplots of geometric mean titter values

The Geometric Mean Ratio (GMR) will be calculated as the exponent of the difference between the natural log transformed titter among those who will receive Jansen (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) and those who will receive Novavax. These

summaries will be repeated for all exploratory research tests used to measure exploratory immunogenicity endpoints at the timepoints for which there are data.

Pairwise comparisons shall be conducted on the GMT response between the 2 booster vaccines both overall and stratified by the primary platform using the student's t-test (*Table 7.16. 1* to *Table 7.16. 4* and Table 7.17. 1 to Table 7.17. 4).

Further, to evaluate the longitudinal changes in the antibody levels, a linear mixed model with restricted cubic splines shall be used [4]. The restricted cubic splines shall be used to estimate the time kinetics curves of antibodies. The general form of the mixed model will be;

$$\ln(Titer_{i,j}) = \beta_0 + \sum_{k=1}^{n} \beta_k S_k(t) + b_{0i} + b_{1i}\, s_1(t) + \cdots + b_{n-1,i}\, s_{n-1}(t) + \mathrm{H}\, X^T + \varepsilon_{i,j}$$

where β_0 and H are the intercept and slope of the model, b_{0i} is the random intercept for each participant, $S_k(t)$ for k=1 ,…,n are restricted cubic splines with n-1 terms and b_{1i} ... $b_{n-1,i}$ are the corresponding random effects. X^T is a matrix of the participants fixed effects which shall be adjusted in the model such as primary vaccine platform, HIV status and age of the participants and e_{ij} is the model error term for participant i at visit day j. Further investigations shall be done using fractional polynomials or natural splines instead of restricted cubic splines to identify which models would provide a better fit to the data.

3.4. Secondary Analysis

3.4.1. Unsolicited and Treatment Emergent Adverse Events

All unsolicited AEs will be recorded in the study database from receipt of first study injection through 28 days after the last study injection administered. At subsequent follow-up visits, only SAEs and new chronic medical conditions will be recorded through the last study visit. The proportion of subjects reporting at least one unsolicited AE will be summarized. Denominators for percentages are the number of subjects who received the injection being summarized.

The incidence of unsolicited adverse events by MedDRA coding shall be reported as incidence proportions and presented in Table 7.13. 1 to Table 7.13. 6 and 7.14.1-7.14.6. Treatment emergent Adverse Events (TEAEs) shall be recorded for all study participants through day 85 of the study. Similar tables to those produced under unsolicited AEs (Table 7.13. 1 to Table 7.13. 6 and 7.14.1-7.14.6) shall be produced on TEAEs.

3.4.2. Adverse events of special interest (AESIs)

Study participants will be evaluated for AESIs up to day 85 and end of study for HIV (-) and HIV (+) participants respectively. AESIs will be assessed as Potential Immune- Mediated Diseases (pIMDs), associated with COVID-19 infection, or any events deemed of special interest by any COVID-19 vaccines received during boosting. Confirmed COVID-19 cases shall be classified as asymptomatic, mild, moderate, or severe along with analysis of symptoms, signs post diagnosis (self-reported).

The Aalen-Johansen estimator of the cumulative incidence function (CIF) for AESI at time t shall be obtained as:

$$CIF\ (t) = \sum_{t_j \leq t} S(t_{j-1})\ \frac{d_j}{n_j}$$

where $s(t)$ is the Kaplan-Meier estimator for the composite endpoint (AESI) at time t_{j-1}, d_j is the number of participants experiencing an AESI at timepoint t_j and n_j is the number of participants under observation before timepoint t_j.

3.4.3. Serious adverse events

The definition of SAEs is available in the most recent version of the protocol version 3.0. In order to provide a description of SAEs, similar outputs outlined in section 3.4.2 shall be used to present summaries of SAEs. All SAEs shall be reported throughout the study within 24 hours of their occurrence.

3.4.4. Immunogenicity heterologous boost

To evaluate the immunogenicity of heterologous boost, the following hypotheses shall be tested:

(i) **H0 (Immune Response IgG):** There is no expected difference in the GMT or GMFR response by ELISA between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

H1 (Immune Response IgG): There is an expected difference in the GMT or GMFR response by ELISA between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

(ii) **H0 (Immune Response Neutralization):** There is no expected difference in the neutralization titre response (absolute or GMFR) between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

H1 (Immune Response Neutralization): There is an expected difference in the GMT response by neutralization titre response (absolute or GMFR) between the 2 vaccine treatment groups at Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

The immunogenicity of the study participants at day 28 compared to baseline shall be assessed using IgG ELISA and VNA titers. A comparison shall be made on the mean and 95% CI for VNA and antibody titers and GMFR (*Table 7.16. 1* to *Table 7.16. 4* and Table 7.17. 1 to Table 7.17. 4) at baseline versus day 28.

3.4.5. Durability of response

A comparison of the durability of response through end of study shall be conducted to investigate the following hypothesis:

H0 (Immune Responses compared to immune competent): There is an expected lower immune response over time (IgG ELISA and neutralization titres) for any one platform or across all platforms after boosting with either Ad26.COV2S1 or NVX-CoV2373.

H1 (Immune Responses compared to immune competent): There is expected immune response over time (IgG ELISA and neutralization titres) for any one platform

or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

A mixed effects model shall be fitted on the log transformed IgG ELISA and neutralization titters while adjusting for the stratification variables. Temporal trends will be modelled using restricted splines and fractional polynomials.

3.4.6. Mucosal immunogenicity of heterologous boost

The GMR and GMFR of the mucosal secretory (S-IgA) measured by ELISA shall be analysed at day 28 verses day 0. The student's T-test, while adjusting for multiple comparison, shall be conducted in order to test the following hypotheses:

(i) **H0 (Immune Response IgG):** There is no expected difference in the GMT or GMFR response by ELISA between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.
H1 (Immune Response IgG): There is an expected difference in the GMT or GMFR response by ELISA between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

(ii) **H0 (Immune Response Neutralization):** There is no expected difference in the neutralization titre response (absolute or GMFR) between baseline and at Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.
H1 (Immune Response Neutralization): There is an expected difference in the GMT response by neutralization titre response (absolute or GMFR) between baseline and Day 28 for any one platform or across all platforms after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373.

Results from this analysis shall be reported in *Table 7.16. 1* to *Table 7.16. 4* and Table 7.17. 1 to Table 7.17. 4.

3.5. Exploratory Analysis

3.5.1. Occurrence of SARS-CoV-2 infections

The Kaplan Meier methods described above shall also be used to estimate the cumulative incidence of virologically confirmed SARS-CoV-2 variants while adjusting for by subject reported symptomatology, duration and severity as well as the stratification randomization variables.

The survival function S(t) shall be defined as the probability of outcome event (symptom resolution or negative rapid Ag test) not occurring up to a particular time of observation (t).

$$s(t) = P(T > t) = 1 - F(t)$$

where T is the random variable denoting time to event, t is the specified time point, P(T>t) is the probability of not experiencing the event up to and including time t and F(T) is the cumulative distribution function. The instantaneous incidence rate at time t shall be estimated by the hazard function h(t) hence the estimation of the Hazard ratio for comparison of 2 or more groups using the cox proportional hazards regression model.

3.5.2. Occurrence of SARS-CoV-2 infection variants

From day 28 to end of study, the incidence of virologically confirmed SARS-CoV-2 variants (e.g., B.1.351, B.1.1.7, B.1.617, B.1.1.529, or others to be identified as the pandemic evolves shall be estimated using incidence proportion. The incidence will be evaluated for participants who develop moderate to severe SARS-CoV-2 symptoms (Table 7.18. 1).

3.5.3. Cell Mediated Immune response of Ad26.COV2S1 and NVX-CoV2372 vaccines

Peripheral Blood Mononuclear Cells (PBMCs), measured by ELISPOT on Day 7 following booster vaccine shall be expressed as the mean number of spot-forming units / 3×10^6

peripheral blood mononuclear cells after subtraction of the background value. These shall be presented as scatter plots of IFN-ϒ and Granzime B cytokines to compare day 7 to day 28.

3.5.4. Identify threshold of immune protection for HIV (+) and (-) participants

Breakthrough cases shall constitute all participants in the intent-to-treat analysis set who received at least one dose of the study booster vaccine and contributed data on SARS-CoV-2 after day 28. For this analysis, we shall investigate the following hypothesis:

H0 (SARS-CoV-2 breakthrough infections): There is no expected difference in breakthrough SARS-COV2 infections after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373 (across primary vaccine platforms).
H1 (SARS-CoV-2 breakthrough infections): There is an expected difference in breakthrough SARS-COV2 infections after boosting with either Ad26.COV2S1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines) or NVX-CoV2373 (across primary vaccine platforms).

The Kaplan-Meir methods discussed above shall be used to estimate SARS-CoV-2 cumulative incidence in moderate and severe cases by variants of concern.

3.5.5. Changes in control of HIV infection

In this objective, changes in control of HIV infections shall be assessed by the viral loads and CD4 counts in the HIV(+) cohort. The natural log transformations of these parameters shall be modelled using mixed effects regression models while adjusting for the stratification randomization variables.

3.6. Statistical Considerations

3.6.1. Missing baseline data

There is a low possibility of missing data at baseline. However, if this occurs then the cause of the missingness shall be investigated and addressed in analysis using appropriate methods [5].

3.6.2. Missing safety outcome data

No imputation will be done on the diary data as these data will be missing completely at random.

3.6.3. Missing immunogenicity outcome data

The level and pattern of outcome missing data at baseline and follow up will be reported. The potential causes of any missing data will be investigated and documented as far as possible. Any missing data will be dealt with using methods appropriate to the conjectured missing mechanism and level of missingness.

3.7. Reporting Conventions

Statistical significance shall be considered with p-values <0.05. In addition, p-values ≥ 0.0001 and ≤0.9999 will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.0001" while p-values greater than 0.9999 will be reported as " >0.9999". The mean, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles, such as median, or minimum and maximum will use the same number of decimal places as the original data. Proportions will be presented as two decimal places; values <0.01 will be presented as "<0.01". Percentages will be reported to the nearest 1 decimal place; values <1% will be presented as "<1%".

4. Analysis visits

Summary visits and analysis windows are specified in the table below.

Table 7: Scheduled visits

Analysis Visit	Study day/month	Analysis Window (days)
1 (Baseline / Screening)	Days -85 to 0	7
2	Day 0	0
3	Day 7	7
4	Day 28	7
5	Day 85	15
6	Month 6	±15
7	Month 12	±15
8	Month 18	±15

References

1. Philip Ryan, 1997. "RALLOC: Stata module to design randomized controlled trials," Statistical Software Components S319901, Boston College Department of Economics, revised 28 Jan 2018.

2. Vidarsson G, Dekkers G, Rispens T. IgG Subclasses and Allotypes: From Structure to Effector Functions. Front Immunol 2014; 5. Available at: https://www.frontiersin.org/article/10.3389/fimmu.2014.00520. Accessed 24 February 2022.

3. Aickin M, Gensler H. Adjusting for multiple testing when reporting research results: the Bonferroni vs Holm methods. Am J Public Health 1996; 86:726–728.

4. Royston, P. and Altman, D.G. (1994), Regression Using Fractional Polynomials of Continuous Covariates: Parsimonious Parametric Modelling. Journal of the Royal Statistical Society: Series C (Applied Statistics), 43: 429-453. https://doi.org/10.2307/2986270

5. White IR, Thompson SG. Adjusting for partially missing baseline measurements in randomized trials. Stat Med 2005; 24:993–1007.

APPENDIX

Table 7.1: Disposition of study participants prior to randomization

	Total
Participants with Informed consent	xx
Discontinued before Randomization [1]	xx
Randomized	xx

[1] Participants who signed informed consent but discontinued before randomization were screen failures

Table 7.2: Analysis Sets of all study participants

Analysis Set	mRNA		Adeno26		Inactivated whole virus		Total
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Randomized	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Participants who took study vaccine	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Participants who did not take study vaccine	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Safety Analysis Set [1]	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Intention-to-treat Set [2]	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Immunogenicity analysis set [3]	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

[1] All randomised participants who receive at least one dose of the study vaccine.

[2] All randomised participants classified by the study group.

[3] All participants in the intent-to-treat analysis set who receive study vaccine, have a baseline and at least 1 post-vaccination sample for which valid results were reported for the test being analysed, and did not receive any COVID-19 vaccine or monoclonal antibody outside of the study

Table 7.3: Participant Randomization

Analysis Set	mRNA	Adeno26	Inactivated whole virus	Total
	(n=xx)	(n=xx)	(n=xx)	(n=xx)
HIV (+)				
12-17 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
18-64 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
HIV (-)				
12-17 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
18-64 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.4: Booster vaccine disposition

Parameter		mRNA		Adeno26		Inactivated whole virus		Total
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Treatment Discontinuation	No	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Yes	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Booster vaccine status	Completed							
	Adverse Event	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Death	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Lost to Follow-up	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Protocol deviation	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Withdrawal by subject	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Non-compliance with study drug	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Other	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Follow-up Discontinuation	No	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Yes	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Primary Follow-up Status	Completed	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Adverse Event	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Death	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Lost to Follow-up	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Withdrawal by subject	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Other	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.5: Major protocol deviations

	mRNA		Adeno26		Inactivated whole virus		Total
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Any Deviation	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
PD 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
PD 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
PD 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
PD 4	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
PD 5	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
PD 6	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.6 1: Demographic characteristics of all study patients

	mRNA		Adeno26		Inactivated whole virus		Total
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	
Total	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Age (years)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Sex / Gender							
Male	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Female	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Child Bearing potential [1]							
Yes	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
No	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Type if contraception							
Condoms	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Diaphragm with spermicide	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Cervical cap with spermicide	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Intrauterine device	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Oral or patch contraceptives	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Hormonal Contraceptives implants or injection	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Abstinence	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Race							
<option1>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option2>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option3>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Ethnicity							
<option1>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option2>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option3>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Country							
Kenya	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
DRC	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Rwanda	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Height (cm)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Weight (kg)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
BMI (kg/m^2)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

[1] Female participants only who: (i) experienced menarche, (ii) were not surgically sterile, or (iii) were not postmenopausal

Table 7.6 2: Demographic characteristics of all study participants who were HIV (+)

	mRNA		Adeno26		Inactivated whole virus		Total
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	
Total	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Age (years)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Sex / Gender							
Male	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Female	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Child Bearing potential [1]							
Yes	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
No	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Type if contraception							
Condoms	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Diaphragm with spermicide	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Cervical cap with spermicide	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Intrauterine device	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Oral or patch contraceptives	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Hormonal Contraceptives implants or injection	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Abstinence	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Race							
<option1>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option2>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option3>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Ethnicity							
<option1>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option2>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option3>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Country							
Kenya	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
DRC	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Rwanda	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Height (cm)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Weight (kg)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
BMI (kg/m^2)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

[1] Female participants only who: (i) experienced menarche, (ii) were not surgically sterile, or (iii) were not postmenopausal

Table 7.6 3: Demographic characteristics of all study participants who were HIV (-)

	mRNA		Adeno26		Inactivated whole virus		Total
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	
Total	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Age (years)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Sex / Gender							
Male	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Female	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Child Bearing potential [1]							
Yes	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
No	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Type if contraception							
Condoms	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Diaphragm with spermicide	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Cervical cap with spermicide	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Intrauterine device	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Oral or patch contraceptives	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Hormonal Contraceptives implants or injection	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Abstinence	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Race							
<option1>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option2>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option3>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Ethnicity							
<option1>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

<option2>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
<option3>	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Country							
Kenya	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
DRC	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Rwanda	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Height (cm)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Weight (kg)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

BMI (kg/m^2)							
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

[1] Female participants only who: (i) experienced menarche, (ii) were not surgically sterile, or (iii) were not postmenopausal

Table 7.7.1: Medical History of all study participants

System Organ Class Preferred Term	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.7. 2: Medical History of HIV (+) study participants only

System Organ Class Preferred Term	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.7. 3: Medical History of HIV (-) study participants

System Organ Class Preferred Term	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Preferred Term 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.7. 4: All participants with pre-existing medical conditions by MedDRA System Organ Class

MedDRA System Organ Class	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Any SOC	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 4	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 5	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 6	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.7. 5: HIV (+) Participants with pre-existing medical conditions by MedDRA System Organ Class

MedDRA System Organ Class	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Any SOC	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 4	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 5	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 6	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.7. 6: HIV (-) Participants with pre-existing medical conditions by MedDRA System Organ Class

MedDRA System Organ Class	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Any SOC	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 4	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 5	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 6	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.8 1: Vital Signs of all study participants

	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Systolic blood pressure								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Diastolic blood pressure								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Pulse/ Heart rate								

N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Pulse/ Heart rate								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Respiratory Rate								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Temperature								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Table 7.8 2: Vital Signs of HIV (+) study participants

	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Systolic blood pressure								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Diastolic blood pressure								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Pulse/ Heart rate								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Pulse/ Heart rate								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Respiratory Rate								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Temperature								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Table 7.8 3: Vital Signs of HIV (-) study participants

	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Systolic blood pressure								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Diastolic blood pressure								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Pulse/ Heart rate								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Pulse/ Heart rate								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Respiratory Rate								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Temperature								
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Table 7.9. 1: Number and percentage of all subjects experiencing solicited adverse events

	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)

Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Erythema or redness								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Induration or swelling								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.9. 2: Number and percentage of subjects experiencing solicited adverse events for HIV (+) participants

	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Erythema or redness								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Induration or swelling								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.9. 3: Number and percentage of subjects experiencing solicited adverse events for HIV (-) participants

	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Erythema or redness								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Induration or swelling								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.9. 4: Number and percentage of subjects experiencing solicited adverse events for participants aged 12-17 years

	mRNA	
	Janssen	Novavax
	(n=xx)	(n=xx)
Pain or tenderness	x(x.xx%)	x(x.xx%)
Erythema or redness		
≤ 15 years	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)
Induration or swelling		
≤ 15 years	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)
Pruritus	x(x.xx%)	x(x.xx%)
Nausea/Vomiting	x(x.xx%)	x(x.xx%)
Diarrhea	x(x.xx%)	x(x.xx%)
Headache	x(x.xx%)	x(x.xx%)
Fatigue	x(x.xx%)	x(x.xx%)
Myalgia	x(x.xx%)	x(x.xx%)

Table 7.9. 5: Number and percentage of subjects experiencing solicited adverse events for participants aged 18-44 years

	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Erythema or redness								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Induration or swelling								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.9. 6: Number and percentage of subjects experiencing solicited adverse events for participants aged 45-64 years

	mRNA		Adeno26		Inactivated whole virus		Total	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Erythema or redness								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Induration or swelling								
≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.10. 1: Number and percentage of all subjects experiencing solicited adverse events by country

		mRNA		Adeno26		Inactivated whole virus		Total	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
Country		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

DRC	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Rwanda	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.10. 2: Number and percentage of subjects experiencing solicited adverse events by country for HIV (+) participants

		mRNA		Adeno26		Inactivated whole virus		Total	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
Country		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

DRC	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
Rwanda	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.10. 3: Number and percentage of subjects experiencing solicited adverse events by country for HIV (-) participants

		mRNA		Adeno26		Inactivated whole virus		Total	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
Country		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
DRC	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Rwanda	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.10. 4: Number and percentage of subjects experiencing solicited adverse events by country for participants aged 12-17 years

		mRNA	
		Janssen	Novavax
Country		(n=xx)	(n=xx)
Kenya	Pain or tenderness	x(x.xx%)	x(x.xx%)
	Erythema or redness		
	≤ 15 years	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)
	Induration or swelling		
	≤ 15 years	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)

	Myalgia	x(x.xx%)	x(x.xx%)
DRC	Pain or tenderness	x(x.xx%)	x(x.xx%)
	Erythema or redness		
	≤ 15 years	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)
	Induration or swelling		
	≤ 15 years	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)

Rwanda	Pain or tenderness	x(x.xx%)	x(x.xx%)
	Erythema or redness		
	≤ 15 years	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)
	Induration or swelling		
	≤ 15 years	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)

Table 7.10. 5: Number and percentage of subjects experiencing solicited adverse events by country for participants aged 18-44 years

		mRNA		Adeno26		Inactivated whole virus		Total	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
Country		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
DRC	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Rwanda	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.10. 6: Number and percentage of subjects experiencing solicited adverse events by country for participants aged 45-64 years

		mRNA		Adeno26		Inactivated whole virus		Total	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
Country		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
DRC	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Rwanda	Pain or tenderness	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Erythema or redness								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Induration or swelling								
	≤ 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	> 15 years	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Pruritus	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Nausea/Vomiting	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Diarrhea	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Headache	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Fatigue	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	Myalgia	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

Table 7.11. 1: Number and percentage of subjects experiencing solicited adverse events by MedDRA system Organ Class

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.11. 2: Number and percentage of subjects experiencing solicited adverse events by MedDRA system Organ Class for HIV (+) participants

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.11. 3: Number and percentage of subjects experiencing solicited adverse events by MedDRA system Organ Class for HIV (-) participants

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.11. 4: Number and percentage of subjects experiencing solicited adverse events by MedDRA system Organ Class for participants aged 12-17 years

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)	
		Janssen	Novavax
		(n=xx)	(n=xx)
Overall			
Any SOC	Any PT	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)
…			

Table 7.11. 5: Number and percentage of subjects experiencing solicited adverse events by MedDRA system Organ Class for participants aged 18-44 years

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.11. 6: Number and percentage of subjects experiencing solicited adverse events by MedDRA system Organ Class for participants aged 45-64 years

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.12. 1: Number and percentage of subjects by country experiencing solicited adverse events by MedDRA system Organ Class

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.12. 2: Number and percentage of subjects by country experiencing solicited adverse events by MedDRA system Organ Class for HIV (+) participants

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.12. 3: Number and percentage of subjects by country experiencing solicited adverse events by MedDRA system Organ Class for HIV (-) participants

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.12. 4: Number and percentage of subjects by country experiencing solicited adverse events by MedDRA system Organ Class for participants aged 12-17 years

Country	MedDRA System Organ Class	MedDRA Preferred Term
Kenya	Overall	
	Any SOC	Any PT
	SOC 1	PT 1
		PT 2
		PT 3
	SOC 2	PT 1
		PT 2
		PT 3
	…	
DRC	Overall	
	Any SOC	Any PT

	SOC 1	PT 1
		PT 2
		PT 3
	SOC 2	PT 1
		PT 2
		PT 3
	…	
Rwanda	Overall	
	Any SOC	Any PT
	SOC 1	PT 1
		PT 2
		PT 3
	SOC 2	PT 1
		PT 2
		PT 3
	…	

Table 7.12. 5: Number and percentage of subjects by country experiencing solicited adverse events by MedDRA system Organ Class for participants aged 18-44 years

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.12. 6: Number and percentage of subjects by country experiencing solicited adverse events by MedDRA system Organ Class for participants aged 45-64 years

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.13. 1: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.13. 2: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for HIV (+) participants

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.13. 3: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for HIV (-) participants

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.13. 4: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for participants aged 12-17 years

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)	
		Janssen	Novavax
		(n=xx)	(n=xx)
Overall			
Any SOC	Any PT	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)
…			

Table 7.13. 5: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for participants aged 18-44 years

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

…									

Table 7.13. 6: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for participants aged 45-64 years

MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
		Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
		(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall									
Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…									

Table 7.14. 1: Number and percentage of subjects by country experiencing unsolicited adverse events by MedDRA system Organ Class

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.14. 2: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for HIV (+) participants

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.14. 3: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for HIV (-) participants

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.14. 4: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for participants aged 12-17 years

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)	
			Janssen	Novavax
			(n=xx)	(n=xx)
Kenya	Overall			
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)
	…			
DRC	Overall			
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)

	SOC 1	PT 1	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)
	…			
Rwanda	Overall			
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)
	…			

Table 7.14. 5: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for participants aged 18-44 years

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.14. 6: Number and percentage of subjects experiencing unsolicited adverse events by MedDRA system Organ Class for participants aged 45-64 years

Country	MedDRA System Organ Class	MedDRA Preferred Term	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
			Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
			(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Kenya	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
DRC	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)

	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									
Rwanda	Overall									
	Any SOC	Any PT	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 1	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	SOC 2	PT 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
		PT 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
	…									

Table 7.15. 1: Safety Analysis- reactogenicity by observed/reported AEs

Primary vaccine platform		AE present	AE absent	p-value [1]
Overall	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
mRNA	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Adeno 26	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Inactivated	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	

[1] p-value reported from the chi-square test or the Fishers exact test as appropriate.

Table 7.15. 2: Safety Analysis- reactogenicity by observed/reported AEs for HIV(+) participants.

Primary vaccine platform		AE present	AE absent	p-value [1]
Overall	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
mRNA	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Adeno 26	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Inactivated	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	

[1] p-value reported from the chi-square test or the Fishers exact test as appropriate.

Table 7.15. 3: Safety Analysis- reactogenicity by observed/reported AEs for HIV(-) participants.

Primary vaccine platform		AE present	AE absent	p-value [1]
Overall	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
mRNA	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Adeno 26	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Inactivated	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	

[1] p-value reported from the chi-square test or the Fishers exact test as appropriate.

Table 7.15. 4: Safety Analysis- reactogenicity by observed/reported AEs for participants aged 12-17 years.

Primary vaccine platform		AE present	AE absent	p-value [1]
mRNA	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	

[1] p-value reported from the chi-square test or the Fishers exact test as appropriate.

Table 7.15. 5: Safety Analysis- reactogenicity by observed/reported AEs for participants aged 18-44 years.

Primary vaccine platform		AE present	AE absent	p-value [1]
Overall	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
mRNA	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Adeno 26	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Inactivated	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	

[1] p-value reported from the chi-square test or the Fishers exact test as appropriate.

Table 7.15. 6: Safety Analysis- reactogenicity by observed/reported AEs for participants aged 45-64 years.

Primary vaccine platform		AE present	AE absent	p-value [1]
Overall	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
mRNA	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Adeno 26	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	
Inactivated	Novavax	xx (xx.x)	xx (xx.x)	x.xxx
	Jansen	xx (xx.x)	xx (xx.x)	

[1] p-value reported from the chi-square test or the Fishers exact test as appropriate.

Table 7.16. 1: Geometric Mean Titers (GMT), Geometric Mean Ratio (GMR) results with 95% CI at baseline and day 28 for HIV (+) participants

		Baseline		Day 28				
Primary Platform		n	GMT (95% CI)	n	GMT (95% CI)	GMT Comparison (p-value)	GMR (95% CI)	GMR Comparison (p-value)
Overall	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
mRNA	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Adeno26	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Inactivated whole virus	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

Table 7.16. 2: Geometric Mean Titers (GMT), Geometric Mean Ratio (GMR) results with 95% CI at baseline and day 28 for HIV (+) participants aged 12-17 years.

<

		Baseline		Day 28				
Primary Platform		n	GMT (95% CI)	n	GMT (95% CI)	GMT Comparison (p-value)	GMR (95% CI)	GMR Comparison (p-value)
mRNA	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

Table 7.16. 3: Geometric Mean Titers (GMT), Geometric Mean Ratio (GMR) results with 95% CI at baseline and day 28 for HIV (+) participants aged 18-44 years

		Baseline		Day 28				
Primary Platform		n	GMT (95% CI)	n	GMT (95% CI)	GMT Comparison (p-value)	GMR (95% CI)	GMR Comparison (p-value)
Overall	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
mRNA	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Adeno26	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Inactivated whole virus	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

Table 7.16. 4: Geometric Mean Titers (GMT), Geometric Mean Ratio (GMR) results with 95% CI at baseline and day 28 for HIV (+) participants aged 45-64 years

		Baseline		Day 28				
Primary Platform		n	GMT (95% CI)	n	GMT (95% CI)	GMT Comparison (p-value)	GMR (95% CI)	GMR Comparison (p-value)
Overall	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
mRNA	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Adeno26	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Inactivated whole virus	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
	Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

Table 7.17. 1: Geometric Mean Titers (GMT), Geometric Mean Ratio (GMR) results with 95% CI at baseline and day 28 by HIV status of the participants

			Baseline		Day 28				
Primary Platform	HIV category	Booster Vaccine	n	GMT (95% CI)	n	GMT (95% CI)	GMT Comparison (p-value)	GMR (95% CI)	GMR Comparison (p-value)
Overall	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
mRNA	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Adeno26	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	

		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

Table 7.17. 2: Geometric Mean Titers (GMT), Geometric Mean Ratio (GMR) results with 95% CI at baseline and day 28 by HIV status of the participants aged 12-17 years.

			Baseline		Day 28				
Primary Platform	HIV category	Booster Vaccine	n	GMT (95% CI)	n	GMT (95% CI)	GMT Comparison (p-value)	GMR (95% CI)	GMR Comparison (p-value)
mRNA	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

Table 7.17. 3: Geometric Mean Titers (GMT), Geometric Mean Ratio (GMR) results with 95% CI at baseline and day 28 by HIV status of the participants aged 18-44 years

			Baseline		Day 28				
Primary Platform	HIV category	Booster Vaccine	n	GMT (95% CI)	n	GMT (95% CI)	GMT Comparison (p-value)	GMR (95% CI)	GMR Comparison (p-value)
Overall	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
mRNA	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Adeno26	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

Table 7.17. 4: Geometric Mean Titers (GMT), Geometric Mean Ratio (GMR) results with 95% CI at baseline and day 28 by HIV status of the participants aged 45-64 years

			Baseline		Day 28				
Primary Platform	HIV category	Booster Vaccine	n	GMT (95% CI)	n	GMT (95% CI)	GMT Comparison (p-value)	GMR (95% CI)	GMR Comparison (p-value)
Overall	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
mRNA	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			
Adeno26	HIV (+)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	x.xxx
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

	HIV (-)	Janssen	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)	x.xxx	xx.x (xx.x,xx.x)	
		Novavax	xx	xx.x (xx.x,xx.x)	xx	xx.x (xx.x,xx.x)			

Table 7.18. 1: Number and percentage of all subjects with virologically confirmed SARS-CoV-2 variants by country

	mRNA (n=xx)		Adeno26 (n=xx)		Inactivated whole virus (n=xx)		Total (n=xx)	
	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax	Janssen	Novavax
SARS-CoV2 variants	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)	(n=xx)
Overall	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 4	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…								
Kenya								
Overall	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 4	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…								

DRC								
Overall	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 4	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…								
Rwanda								
Overall	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 1	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 2	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 3	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
variant 4	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)	x(x.xx%)
…								

LISTINGS

Listing 8.1.1: Solicited Adverse Events

Subject ID	Country	Treatment Group	Post vaccine day	Adverse Event	Assessment*	<symptom1>	<symptom2>	<symptom3>
					MA			
					Clinic			

* MA=Data reported by subject on the diary and reviewed by the study staff, Clinic=Data collected by the clinic study staff during physical exam or symptom assessment

Listing 8.1.2: Unsolicited Adverse Events

Subject ID	Country	Treatment Group	AE number	Adverse Event	MedDRA Preferred Term	AE onset Date	Date of resolution	Subject Discontinued due to AE