Janssen Vaccines & Prevention B.V. *

Statistical Analysis Plan

A Multi-country, Prospective, Clinical Safety Study of Participants Exposed to the Candidate Ebola Vaccines Ad26.ZEBOV and/or MVA-BN-Filo

Protocol VAC52150EBL4001; Phase 3

VAC52150 (Ad26.ZEBOV/MVA-BN-Filo [MVA-mBN226B])

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Prepared by: Janssen Vaccines & Prevention B.V.
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Compliance: The study described in this report was performed according to the principles of Good Clinical Practice (GCP).

TABLE OF CONTENTS

VERSION HISTORY

Table 1 – SAP Version History Summary

SAP Version	Approval Date	Change	Rationale
1.0		Not Applicable	Initial release

1. INTRODUCTION

This statistical analysis plan (SAP) contains the definitions of analysis sets, derived variables, and statistical methods that will be used to evaluate the safety of the roll-over study VAC52150EBL4001, comprising participants from phase 1, 2, and 3 studies with Ad26.ZEBOV/MVA-BN-Filo (MVA-mBN226B) vaccinations. This SAP will include the details of the statistical analysis of the data collected for the final analysis. This document is developed in line with the Clinical Protocol VAC52150EBL4001 Amendment 2 approved on March 2nd 2017.

This SAP will be applicable to the Full Analysis Set which includes all participants who were enrolled in this study and have at least one post-baseline visit, regardless of the occurrence of protocol violations. Restricted Analysis Set includes all participants who were enrolled in this study and have at least one post-baseline visit, have no major protocol deviations deemed to affect safety endpoints, and have not been enrolled in any other clinical study.

1.1. Objectives

The study objectives are:

- To collect serious adverse event information from participants exposed to Ad26.ZEBOV and/or MVA-BN-Filo in a Phase 1, 2, or 3 clinical studies, for a total of 60 months after prime vaccination (including the duration in the participant's original study).
- To collect pregnancy outcomes (including spontaneous/elective abortion, intrauterine death/stillbirth, information on delivery) and serious adverse event information during pregnancy from female participants who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV in a Phase 1, 2, or 3 clinical study.
- To collect serious adverse event information for up to 60 months after birth from children born to female participants who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV in a Phase 1, 2, or 3 clinical study.

1.2. Study Design

This is a multi-country, prospective, long-term clinical safety study designed to extend the total follow-up period of vaccinated participants up to 60 months (including the duration in the participant's original study), to allow collection of serious adverse events and pregnancy outcomes (including spontaneous/elective abortion, intrauterine death/stillbirth, information on delivery) following administration of Ad26.ZEBOV and/or MVA-BN-Filo for the prevention of Ebola virus disease among participants who participated in a Phase 1, 2, or 3 clinical study. In addition, offspring from vaccinated female participants who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV in a Phase 1, 2, or 3 clinical study will be followed up to 60 months after birth. Up to approximately 3,000 participants may potentially be enrolled in this study, based on the number of exposed participants in the contributing Phase 1, 2, or 3 clinical studies.

Data collection was as follows for the 3 cohorts:

Cohort 1: Data for participants vaccinated with Ad26.ZEBOV and/or MVA-BN-Filo (or placebo) in a Phase 1, 2, or 3 clinical study, and who consent to participation in the current study will be collected in 6-month intervals. Data collection will continue for a total of 60 months after Dose 1 (including the duration in the participant's original study).

Cohort 2: Data on the pregnancy outcome of female participants who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo (or placebo) or within 3 months after vaccination with Ad26.ZEBOV (or placebo) in a Phase 1, 2, or 3 clinical study and who consent to participation in the current study will be collected at notification of the pregnancy and at the end of the pregnancy. These participants will be followed in Cohort 2 up to the end of their pregnancy. Thereafter, female participants will continue to be followed in Cohort 1 (to reach a total of 60 months follow-up after Dose 1 vaccination, including the duration in the participants original study); live-born children will be followed in Cohort 3.

Cohort 3: Data for children born to female participants exposed to Ad26.ZEBOV and/or MVA-BN-Filo (or placebo) in a Phase 1, 2, or 3 clinical study who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo (or placebo) or within 3 months after vaccination with Ad26.ZEBOV (or placebo) and for whom consent for the current study is given, will be collected in 6-month intervals, and up to 60 months after birth.

The study consists of an enrollment visit, a number of follow-up contacts, and an end-of-study contact. These contacts are preferably conducted by phone; if not possible, a study site visit needs to be organized. Preferably, offspring from vaccinated female participants will visit the study site for every study visit. If not possible, the child may be visited at home by study site staff or a qualified health care worker for data collection.

COHORT 1: VACCINATED PARTICIPANTS

Data collection schedule for participants exposed to Ad26.ZEBOV and/or MVA-BN-Filo (or placebo) in a Phase 1, 2, or 3 clinical study:

	Visit 1[a]	Contact 2[a]	Subsequent Contacts[a]	End of Study[a]
	Baseline (Start of Data Collection)[b]	**Month 6**	**Every 6 months**	**After 60 Months of Follow Up[c]**
Participant Information				
Participant Consent[d]	**X**			
Selection Criteria	**X**			
Demographics[e]	**X**			
Ongoing Participant Review				
Serious Adverse Events[e,f]	**X**	**X**	**X**	**X**
Medication and Vaccinations[e,g]	**X**	**X**	**X**	**X**
Study Completion/Withdrawal				
End-of-Study Form				**X**[h]

a. Only the first visit is a study site visit (and may coincide with the last visit in the participant's original study); data collection at other time points will preferably occur through phone calls. If not possible by phone, a study site visit needs to be organized.
b. Data collection can start when a signed informed consent form (ICF) is available for the current study. Preferably, this occurs at the last visit of the participant's original study. If this is not possible, baseline data will be collected when a signed ICF is available and data will be captured retrospectively from the participant's last visit in the original study up to the moment of enrollment in the current study.
c. The participant should be followed for a total of 60 months after Dose 1, including the duration in the participant's original study.
d. Before the start of data collection in this study, all participants and/or their legally-acceptable representative (where applicable) must sign an ICF for the current study indicating that he or she understands the purpose of and procedures required for the study and is willing to participate in the study.
e. Relevant data will be copied from the analysis data set of the participant's original study. Any relevant new information should be added in the Case Report Form (CRF) of the current study.
f. All serious adverse events are to be documented for a total of 60 months after dose 1 vaccination (including the duration in the participant's original study).
g. Any medication taken within a period of 30 days prior to the onset of a serious adverse event and up to the resolution of the serious adverse event.
h. When an enrolled participant completes or withdraws from the study, or is lost to follow-up, the investigator will complete the end-of-study form for the individual participant and provide a specific date for the end-of-study observation(s).

COHORT 2: PREGNANCY OUTCOMES

Data collection schedule for female participants who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo (or placebo) or within 3 months after vaccination with Ad26.ZEBOV (or placebo) in a Phase 1, 2, or 3 clinical study:

	Visit 1[a]	**End of Pregnancy Follow-Up[a]**
	Baseline (Start of Data Collection)[b]	**End of Pregnancy**
Participant Information		
Participant Consent[c]	**X**	
Selection Criteria	**X**	
Demographics[d]	**X**	
Ongoing Participant Review		
Serious Adverse Events[d,e]	**X**	**X**
Medication and Vaccinations[e,f]	**X**	**X**
Pregnancy Follow-Up[g]	**X**	**X**
Study Completion/Withdrawal		
End-of-Study Form[h]		**X**[i]

a. Only the first visit is a study site visit; data collection at the end of the pregnancy will preferably occur through a phone call. If not possible by phone, a study site visit needs to be organized.
b. Data collection can start when a signed ICF is available for the current study. Preferably, this occurs at the last visit of the participant's original study. If this is not possible, baseline data will be collected when a signed ICF is available and data will be captured retrospectively from the participant's last visit in the original study up to the moment of enrollment in the current study.
c. Before the start of data collection in this study, all participants and/or their legally-acceptable representative (where applicable) must sign an ICF for the current study indicating that he or she understands the purpose of and procedures required for the study and is willing to participate in the study.
d. Relevant data will be copied from the analysis data set of the participant's original study. Any relevant new information should be added in the CRF of the current study.
e. All serious adverse events in participants exposed to Ad26.ZEBOV (or placebo) and/or MVA-BN-Filo (or placebo) are to be documented. Data collection should start with study enrollment and continue until the end of the pregnancy.
f. Any medication taken within a period of 30 days prior to the onset of a serious adverse event and up to the resolution of the serious adverse event.
g. Information on obstetric history, maternal/paternal risk factors, pregnancy outcome (including spontaneous/elective abortion, intrauterine death/stillbirth, information on delivery).
h. After the pregnancy, female participants will continue to be followed up in Cohort 1. A live-born child will be followed up in Cohort 3.
i. When an enrolled participant completes or withdraws from the study, or is lost to follow-up, the investigator will complete the end-of-study form for the individual participant and provide a specific date for the end-of-study observation(s).

COHORT 3: OFFSPRING

Data collection schedule for children born to female participants who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo (or placebo) or within 3 months after vaccination with Ad26.ZEBOV (or placebo) in a Phase 1, 2, or 3 clinical study:

	Visit 1[a]	Visit 2[a]	Subsequent Visits[a]	End of Study[a]
	Baseline (Start of Data Collection)[b]	**Month 6**	**Every 6 months**	**After 60 Months After Birth**
Participant Information				
Participant Consent[c]	**X**			
Selection Criteria	**X**			
Demographics	**X**			
Medial History[d]				
Ongoing Participant Review				
Serious Adverse Events[e]	**X**	**X**	**X**	**X**
Medication and Vaccinations[f]	**X**	**X**	**X**	**X**
Growth Measurements[g]	**X**	**X**	**X**	**X**
Study Completion/Withdrawal				
End-of-Study Form				**X**[h]

a. Preferably, offspring from vaccinated female participants will visit the study site for every study visit. If not possible, the child may be visited at home by study site staff or a qualified health care worker for data collection.
b. Data collection can start when a signed ICF is available for the current study (at birth or as soon as possible after birth). If this is not possible, baseline data will be collected when a signed ICF is available and data will be captured retrospectively from birth up to the moment of enrollment in the current study.
c. Before the start of data collection in this study, the participant's parent or legally-acceptable representative (where applicable) must sign an ICF for the current study indicating that he or she understands the purpose of and procedures required for the study and is willing to let their child participate in the study.
d. Medical history of the child may include information on birth (preterm/full term), presence of birth defects, medical interventions beyond routine interventions at birth and relevant information from the mother's pregnancy follow-up, family history of growth (details on stature of parents and siblings).
e. All serious adverse events are to be documented. Data collection should start with the time of birth and continue for 60 months.
f. Any medication taken within a period of 30 days prior to the onset of a serious adverse event and up to the resolution of the serious adverse event.
g. Height, weight, growth percentiles.
h. When an enrolled participant completes or withdraws from the study, or is lost to follow-up, the investigator will complete the end-of-study form for the individual participant and provide a specific date for the end-of-study observation(s).

2. STATISTICAL HYPOTHESES

This is a descriptive study to document the long-term safety profile of Ad26.ZEBOV and MVA-BN-Filo and to address gaps in the currently available data for the risks of Ad26.ZEBOV and/or MVA-BN-Filo.

As this study aims to describe the data for benefit-risk assessment purposes, no hypotheses are prespecified.

3. SAMPLE SIZE DETERMINATION

Participants from:

- 5 Phase 1 clinical studies (VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, and VAC52150EBL1005),
- 3 Phase 2 clinical studies (VAC52150EBL2001, VAC52150EBL2002, and VAC52150EBL2003)
- 3 Phase 3 clinical studies (VAC52150EBL3001, VAC52150EBL3002, and VAC52150EBL3003),
- children born to female participants who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo (or placebo) or within 3 months after vaccination with Ad26.ZEBOV (or placebo) in a phase 1, 2, or 3 clinical study.

After team discussions, no participants from studies VAC52150EBL1005, VAC52150EBL2003, and VAC52150EBL3001 are included (VAC52150EBL1005 investigated another regimen, VAC52150EBL2003 had no eligible studies, and VAC52150EBL3001 transited to VAC52150EBL3005).

4. POPULATIONS (ANALYSIS SETS) FOR ANALYSIS

Analysis Sets	**Description**
Enrolled	All eligible participants (Section 3) who signed IC.
Full Analysis Set (FAS)	Includes all participants who were enrolled in this study and have at least one post-baseline visit, regardless of the occurrence of protocol deviations.
Restricted Analysis Set (RAS)	Includes all participants who were enrolled in this study and have at least one post-baseline visit, have no major protocol deviations deemed to affect safety endpoints, and have not been enrolled in any other clinical study

The study endpoints are analyzed based on the Full Analysis Set as the primary analysis population. Additionally, the study endpoints may be analyzed based on the Restricted Analysis Set as a secondary analysis population (sensitivity analysis), when at least 10% of participants are excluded from the restricted set.

5. STATISTICAL ANALYSES

5.1. General Considerations

Baseline values will be defined as the values or characteristics as recorded in the participant's original study, including demographics, medical, and vaccination history will be summarized by cohort.

Categorical variables will be summarized by frequency distribution (number and percentage of participants) and continuous variables will be summarized by descriptive statistics (including mean, median, and standard deviation). The mean and median will be rounded to one more decimal place than the original data, while the SD and 95% CI to two more decimal places.

For each serious adverse event, the percentage of participants who experience at least 1 occurrence of the given event and the incidence rate, expressed as number of events per 1000 person years (where applicable) with corresponding 2-sided 95% confidence intervals will be provided, for each cohort.

The incidence rate of SAEs, and frequencies of pregnancy by pregnancy outcomes (including spontaneous/elective abortion, intrauterine death/stillbirth, and information on delivery) and of live-born children will be summarized. Only pregnancies with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV, and live-born children from these pregnancies, will be included.

Incidence rate will be defined as follows:

$$\text{Incidence rate} = \frac{\text{numbers of events}}{\text{Sum of person time}}$$

Person time is defined as the time between first vaccination and data cutoff or completion date, whichever occurs first (for completers), or first vaccination and discontinuation date (for non-completers). Incidence rates will be reported per 1000 person-years.

The 95% confidence interval is derived using an exact Poisson approach:

$$Lower\ limit = \frac{CINV(0.025, 2 * P)}{2}/n)$$

$$Upper\ lmimit = \frac{CINV\big(0.975, 2 * (p+1)\big)}{2}/n$$

Where p = number of events, n = sum of follow-up time. The CINV function returns the q^{th} quantile (depending on alpha) from the chi-square distribution with parameters probability and degrees of freedom.

5.2. Dispositions

For each cohort, disposition tables will be produced. These tables will consist of:

Cohort 1:

- Participants enrolled
- End of study information (completed, withdrawn from the study, or lost to follow-up)

Cohort 2:

- Participants enrolled
- End of study information (completed withdrawn from the study, or lost to follow-up)
- Participants followed in Cohort 1 (after the pregnancy)

Cohort 3:

- Number of new-born children
- End of study (completed, withdrawn from study, or lost-to follow-up)

5.3. Participant Information

Baseline characteristics as recorded in the participant's original study, including demographics, medical, and vaccination history are summarized by cohort and original randomization (active vaccine versus control group)

5.4. Primary Endpoint(s) Analysis

The primary endpoint will be analysed based on the Full Analysis Set.

5.4.1. Definition of Endpoint(s)

The following endpoints will be analyzed:

- Incidence of serious adverse events in participants exposed to Ad26.ZEBOV and/or MVA-BN-Filo in a Phase 1, 2, or 3 clinical study, up to 60 months after Dose 1.
- Incidence of pregnancy with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV.
- Incidence of pregnancy by pregnancy outcome.
- Incidence of live-born children from a pregnancy with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV.
- Incidence of serious adverse events in children born from a pregnancy with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV up to 60 months after birth.

5.4.2. Definitions

Serious Adverse Event

A serious adverse event based on ICH and EU Guidelines on Pharmacovigilance for Medicinal Products for Human Use is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening (the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe.)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is a suspected transmission of any infectious agent via a medicinal product
- Is Medically Important
- SAEs leading to study discontinuation (information from the parent studies)

Medical and scientific judgment should be exercised in deciding whether expedited reporting is also appropriate in other situations, such as important medical events that may not be immediately life threatening or result in death or hospitalization but may jeopardize the participant or may require intervention to prevent one of the other outcomes listed in the definition above. These should usually be considered serious.

If a serious and unexpected adverse event occurs for which there is evidence suggesting a causal relationship between the study vaccine and the event, the event must be reported as a serious and unexpected suspected adverse reaction (SUSAR) even if it is a component of the study endpoint (eg, all-cause mortality).

Unlisted (Unexpected) Adverse Event/Reference Safety Information

An adverse event is considered unlisted if the nature or severity is not consistent with the applicable product reference safety information. For Ad6.ZEBOV and MVA-BN-Filo, the expectedness of an adverse event will be determined by whether or not it is listed in the Investigator's Brochure and Addenda, if applicable.

Adverse Event With a Causal Relationship to a Study Vaccine

An adverse event is considered to have a causal relationship to a study vaccine if the attribution is:

Possible

An adverse event that might be due to the use of the study vaccine, an alternative explanation, eg, concomitant drug(s), concomitant disease(s), is inconclusive. The relationship in time is reasonable; therefore, the causal relationship cannot be excluded.

Probable

An adverse event that might be due to the use of the study vaccine, the relationship in time is suggestive. An alternative explanation is less likely, eg, concomitant drug(s), concomitant disease(s).

Very Likely

An adverse event that is listed as a possible adverse reaction and cannot be reasonably explained by an alternative explanation, eg, concomitant drug(s), concomitant disease(s), the relationship in time is very suggestive.

An adverse event is considered to have no causal relationship to the study vaccine if the attribution is:

Not Related

An adverse event that is not related to the use of the study vaccine

Doubtful

An adverse event for which an alternative explanation is more likely, eg, concomitant drug(s), concomitant disease(s), or the relationship in time suggests that a causal relationship is unlikely.

Severity Criteria

An assessment of severity grade will be made using the following general categorical descriptors:

Mild: Awareness of symptoms that are easily tolerated, causing minimal discomfort and not interfering with everyday activities.

Moderate: Sufficient discomfort is present to cause interference with normal activity.

Severe: Extreme distress, causing significant impairment of functioning or incapacitation Prevents normal everyday activities.

The investigator should use clinical judgment in assessing the severity of events not directly experienced by the participant (eg, laboratory abnormalities).

5.4.3. Analysis Methods

5.4.3.1. SAEs

Adverse events are tabulated by presenting the percentage of participants who experienced at least 1 SAE. SAEs will be tabulated by SOC and Preferred Terms, showing the number of participants (and percentages) with at least 1 occurrence.

Adverse events are also tabulated as the number of events per 1000 person-years with corresponding 2-sided 95% confidence interval. This confidence interval will be estimated by means of an exact Poisson model.

Both percentages and incidence rates are presented for:

- Any SAE
- SAEs resulting in death
- Life-threatening SAEs (the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe.)
- SAEs requiring inpatient hospitalization or prolongation of existing hospitalization
- SAEs resulting in persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Medically Important SAEs
- SAEs leading to study discontinuation.

Frequencies and incidence rates tables are presented for Adverse events of special interest known for Ad26.ZEBOV and MVA-BN-Filo

5.4.3.2. Pregnancies (Cohort 2)

All initial reports of pregnancy in the Phase 1, 2, or 3 trials with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV in female participants must have been reported to the sponsor by the study-site.

Frequencies and incidence rate tables are created, for participants with:

- spontaneous/elective abortion
- intrauterine death/stillbirth
- serious adverse events occurring in their offspring

After delivery, participants from Cohort 2 will continue in Cohort 1.

5.4.3.3. Growth Measurements (Cohort 3)

Incidence rate is based on the patient-years defined as the time between date of birth and database cutoff or 60 months after birth, whichever happens first.

Height, weight, and growth percentiles are listed.

SAEs in children born from a pregnancy with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV up to 60 months after birth will be listed.

5.4.3.4. Other safety Parameters

Frequency tables of medication taken within a period of 30 days prior to the onset of a serious adverse event and up to the resolution of the serious adverse event or medications taken in relation to serious adverse events are presented by cohort

5.5. Secondary Endpoint(s) Analysis

Primary endpoint analyses are repeated for the Restricted Analysis Set (sensitivity analyses), if at least 10% of the participants are removed from the Restricted Analysis Set.

5.6. Missing Data

Serious Adverse Events: Participants who do not report an event will be considered as participants without an event. An SAE with a missing severity or relationship will be considered as an SAE reported, but will be considered as not reported for the severity or relationship.

For the analysis of concomitant medications within a period of 30 days prior to the onset of a SAE and up to the resolution, the following imputation is used for partial or missing dates of SAEs or concomitant medications:

SAEs:

Onset date

If onset date is completely missing, the date is imputed by the date of first dose (for Cohort 1. For cohort 3, date of birth (if available), or enrollment date is used).

If the onset date is partially missing:

- If only year is given, we assume January 1st of that year
- If only month and year are given, we assume the 1st of that month

Stop date

If the stop date is missing, we assume the SAE is unresolved and ongoing.

If the stop date is partially missing:

- If only year is given, we assume December 31st of that year
- If only month and year given, we assume the last day of that month

Concomitant medication:

- If the start date of medication intake is missing, the medication start date is assumed before the start of the trial
- If stop date of medication intake is missing, the medication intake is considered ongoing at the end of the trial
- If the start date is partially missing: take the first day of the month/year (e.g. 01JANYYYY)

- If the stop date is partially missing, take the last day of the month/year (e.g. 31MARYYYY)

5.7. Other Analyses

For cohort 3, information on birth (preterm, full term) is tabulated. Presence of birth defects and medical interventions beyond routine interventions at birth are listed. The medical history of the child, including information from the mother's pregnancy follow-up, family history of growth (details on stature of parents and siblings, if available) is listed.

Height (cm), weight (kg), and as well as height, weight percentiles are listed at birth and subsequent visits. A graphical presentation of height and weight over time (baseline, and every 6 months post-baseline) is created.

5.8. Interim Analyses

There are no planned interim analyses. However, the accumulating data during study conduct may be used for reporting required for health authority submissions or other purposes. As this is a non-comparative study without formal hypotheses, any interim data may be used for purely administrative purposes without having an impact on study conduct or need for statistical adjustments. All interim reporting must be approved by the study responsible physician and project statistician prior to conduct.

6. SUPPORTING DOCUMENTATION

6.1. Appendix 1 List of Abbreviations

ADaM	Analysis Data Model
AE	adverse event
AESI	adverse event of special interest
BMI	body mass index
CI	confidence interval
CM	concomitant medication
CRF	case report form
CTP	clinical trial protocol
FAS	full analysis set
IR	incidence rate
SAE	serious adverse event
SAP	Statistical Analysis Plan
sSD	standard deviation
SDTM	Study Data Tabulation Model
SE	standard error
WHO	World Health Organization

6.2. Appendix 2 Changes to Protocol-Planned Analyses

The study will be stopped early (data base lock in Q1 2022).

7. REFERENCES

1. Protocol VAC52150EBL4001; Phase 3 AMENDMENT 2: A Multi-country, Prospective, Clinical Safety Study of Subjects Exposed to the Candidate Ebola Vaccines Ad26.ZEBOV and/or MVA-BN-Filo, 2 March 2017

2. Using SAS® to Calculate Incidence and Prevalence Rates in a Dynamic Population (https://www.lexjansen.com/wuss/2012/103.pdf)s