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

Summary

EudraCT number	2015-004139-11
Trial protocol	GB FR
Global end of trial date	13 December 2021

Results information

Result version number	v1 (current)
This version publication date	29 June 2022
First version publication date	29 June 2022

Trial information

Trial identification

Sponsor protocol code	VAC52150EBL4001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02661464
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Vaccines & Prevention B.V.
Sponsor organisation address	Archimedesweg 4-6, Leiden, Netherlands, 2333 CN
Public contact	Clinical Registry Group, Janssen Vaccines & Prevention B.V., ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Vaccines & Prevention B.V., ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 December 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to collect serious adverse event information from subjects exposed to Ad26 vector expressing the glycoprotein of the ebola virus mayinga variant (Ad26.ZEBOV) and/or modified vaccinia ankara bavarian nordic vector expressing multiple filovirus proteins (MVA-BN-Filo) in a Phase 1, 2, or 3 clinical study, for a total of 60 months after prime vaccination (including the duration in the subject's original study).

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice (GCP) and applicable regulatory requirements. Safety evaluations were based upon the serious adverse events reported throughout the study, and on incidence of pregnancy, incidence of pregnancy outcomes (including spontaneous/elective abortion, intrauterine death/stillbirth, information on delivery) and incidence of live-born children.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 May 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Burkina Faso: 79
Country: Number of subjects enrolled	France: 157
Country: Number of subjects enrolled	United Kingdom: 180
Country: Number of subjects enrolled	Kenya: 56
Country: Number of subjects enrolled	Tanzania, United Republic of: 16
Country: Number of subjects enrolled	Uganda: 28
Country: Number of subjects enrolled	United States: 154
Worldwide total number of subjects	670
EEA total number of subjects	157

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	3
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	664
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No pregnant female from Cohort 1 who became pregnant in a Phase 1, 2 or 3 study were enrolled in Cohort 2. Hence Cohort 2 and its related endpoints not reported as planned. Out of 3 pregnant females, 2 did not enroll in current study. 1 completed Phase 1, 2 or 3 study and enrolled in Cohort 1 as she was not pregnant when enrolled in current study.

Pre-assignment

Screening details:

A total of 677 subjects who received Ad26.ZEBOV and/or MVA-BN-Filo or Placebo in a Phase 1, 2 or 3 study were enrolled. Seven subjects were excluded from further analysis as they had no post baseline visits in current study. Therefore, 670 subjects were analysed out which 296 subjects completed the study.

Period 1

Period 1 title	Overall Period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo

Arm description:

Safety data of subjects vaccinated with Ad26 vector expressing the glycoprotein of the Ebola virus mayinga variant (Ad26.ZEBOV) and/or modified vaccinia ankara bavarian nordic vector expressing multiple filovirus proteins (MVA-BN-Filo) in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003 (adults, adolescents and children) and who consented to participate in the current study was collected in 6-month intervals and up to a total of 60 months after vaccination (including the duration in the subject’s original study). No vaccine was to be administered in the current study.

Arm type	Experimental
Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received intramuscular injection of MVA-BN-Filo at specified time points in a Phase 1, 2 or 3 study.

Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received intramuscular injection of Ad26.ZEBOV at specified time points in a Phase 1, 2 or 3 study.

Arm title	Cohort 1: Placebo

Arm description:

Safety data of subjects vaccinated with Ad26.ZEBOV matching placebo and/or MVA-BN-Filo matching placebo in) in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003 (adults, adolescents and children) and who consented to participate in the

current study was collected in 6-month intervals and up to a total of 60 months after vaccination (including the duration in the subject's original study). No vaccine was to be administered in the current study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received intramuscular injection of Ad26.ZEBOV or MVA-BN-Filo matching placebo at specified time points in a Phase 1, 2 or 3 study.

Arm title	Cohort 3: Ad26.ZEBOV and/or MVA-BN-Filo

Arm description:

Safety data of children born to female subjects exposed to Ad26.ZEBOV and/or MVA-BNFilo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003, who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV and for whom consent for the current study was given, was collected in 6-month intervals and up to 60 months after birth. No vaccine was to be administered in the current study.

Arm type	Experimental
Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Children born to females who received intramuscular injection of MVA-BN-Filo matching placebo at specified time points in a Phase 1, 2 or 3 study.

Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Children born to females who received intramuscular injection of Ad26.ZEBOV at specified time points in a Phase 1, 2 or 3 study.

Arm title	Cohort 3: Placebo

Arm description:

Safety data of children born to female subjects exposed to Ad26.ZEBOV matching placebo and/or MVA-BNFilo matching placebo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003, who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo matching placebo or within 3 months after vaccination with Ad26.ZEBOV matching placebo and for whom consent for the current study was given, was collected in 6-month intervals and up to 60 months after birth. No vaccine was to be administered in the current study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Children born to females who received intramuscular injection of Ad26.ZEBOV or MVA-BN-Filo matching placebo at specified time points in a Phase 1, 2 or 3 study.

Number of subjects in period 1	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo	Cohort 1: Placebo	Cohort 3: Ad26.ZEBOV and/or MVA-BN-Filo
Started	614	53	2
Completed	295	0	1
Not completed	319	53	1
Study terminated by sponsor	-	-	1
Unspecified	288	52	-
Lost to follow-up	28	-	-
Withdrawal by subject	3	1	-

Number of subjects in period 1	Cohort 3: Placebo
Started	1
Completed	0
Not completed	1
Study terminated by sponsor	-
Unspecified	1
Lost to follow-up	-
Withdrawal by subject	-

Baseline characteristics

Reporting groups

Reporting group title	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo

Reporting group description:

Safety data of subjects vaccinated with Ad26 vector expressing the glycoprotein of the Ebola virus mayinga variant (Ad26.ZEBOV) and/or modified vaccinia ankara bavarian nordic vector expressing multiple filovirus proteins (MVA-BN-Filo) in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003 (adults, adolescents and children) and who consented to participate in the current study was collected in 6-month intervals and up to a total of 60 months after vaccination (including the duration in the subject's original study). No vaccine was to be administered in the current study.

Reporting group title	Cohort 1: Placebo

Reporting group description:

Safety data of subjects vaccinated with Ad26.ZEBOV matching placebo and/or MVA-BN-Filo matching placebo in) in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003 (adults, adolescents and children) and who consented to participate in the current study was collected in 6-month intervals and up to a total of 60 months after vaccination (including the duration in the subject's original study). No vaccine was to be administered in the current study.

Reporting group title	Cohort 3: Ad26.ZEBOV and/or MVA-BN-Filo

Reporting group description:

Safety data of children born to female subjects exposed to Ad26.ZEBOV and/or MVA-BNFilo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003, who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV and for whom consent for the current study was given, was collected in 6-month intervals and up to 60 months after birth. No vaccine was to be administered in the current study.

Reporting group title	Cohort 3: Placebo

Reporting group description:

Safety data of children born to female subjects exposed to Ad26.ZEBOV matching placebo and/or MVA-BNFilo matching placebo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003, who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo matching placebo or within 3 months after vaccination with Ad26.ZEBOV matching placebo and for whom consent for the current study was given, was collected in 6-month intervals and up to 60 months after birth. No vaccine was to be administered in the current study.

Reporting group values	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo	Cohort 1: Placebo	Cohort 3: Ad26.ZEBOV and/or MVA-BN-Filo
Number of subjects	614	53	2
Title for AgeCategorical			
Units: subjects			

Title for AgeContinuous			
In "Cohort 3: Placebo" arm, 99999 signifies standard deviation could not be estimated as only one subject contributed to the data.			
Units: years			
arithmetic mean	35.6	37	1.2
standard deviation	± 13	± 13.44	± 0.41
Title for Gender			
Units: subjects			
Female	254	24	1

Male	360	29	1

Reporting group values	Cohort 3: Placebo	Total	
Number of subjects	1	670	
Title for AgeCategorical Units: subjects			

Title for AgeContinuous			
In "Cohort 3: Placebo" arm, 99999 signifies standard deviation could not be estimated as only one subject contributed to the data.			
Units: years			
arithmetic mean	1.3		
standard deviation	± 99999	-	
Title for Gender Units: subjects			
Female	0	279	
Male	1	391	

End points

End points reporting groups

Reporting group title	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo

Reporting group description:

Safety data of subjects vaccinated with Ad26 vector expressing the glycoprotein of the Ebola virus mayinga variant (Ad26.ZEBOV) and/or modified vaccinia ankara bavarian nordic vector expressing multiple filovirus proteins (MVA-BN-Filo) in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003 (adults, adolescents and children) and who consented to participate in the current study was collected in 6-month intervals and up to a total of 60 months after vaccination (including the duration in the subject's original study). No vaccine was to be administered in the current study.

Reporting group title	Cohort 1: Placebo

Reporting group description:

Safety data of subjects vaccinated with Ad26.ZEBOV matching placebo and/or MVA-BN-Filo matching placebo in) in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003 (adults, adolescents and children) and who consented to participate in the current study was collected in 6-month intervals and up to a total of 60 months after vaccination (including the duration in the subject's original study). No vaccine was to be administered in the current study.

Reporting group title	Cohort 3: Ad26.ZEBOV and/or MVA-BN-Filo

Reporting group description:

Safety data of children born to female subjects exposed to Ad26.ZEBOV and/or MVA-BNFilo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003, who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV and for whom consent for the current study was given, was collected in 6-month intervals and up to 60 months after birth. No vaccine was to be administered in the current study.

Reporting group title	Cohort 3: Placebo

Reporting group description:

Safety data of children born to female subjects exposed to Ad26.ZEBOV matching placebo and/or MVA-BNFilo matching placebo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003, who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo matching placebo or within 3 months after vaccination with Ad26.ZEBOV matching placebo and for whom consent for the current study was given, was collected in 6-month intervals and up to 60 months after birth. No vaccine was to be administered in the current study.

Primary: Percentage of Subjects With Serious Adverse Events (SAEs)

End point title	Percentage of Subjects With Serious Adverse Events (SAEs)[1]

End point description:

A serious adverse event is any untoward medical occurrence that at any dose results in death, is life-threatening, 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. Full Analysis Set (FAS) included all subjects who were enrolled in this study and had at least one post baseline visit, regardless of the occurrence of protocol deviations.

End point type	Primary

End point timeframe:

Up to 60 months after dose 1 vaccination (including the duration in the Subjects original study)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo	Cohort 1: Placebo	Cohort 3: Ad26.ZEBOV and/or MVA-BN-Filo	Cohort 3: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	614	53	2	1
Units: Percentage of subjects				
number (not applicable)	49	1	2	1

Statistical analyses

No statistical analyses for this end point

Primary: Number 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

End point title	Number 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[2][3]

End point description:

Number of live-born children from a pregnancy with estimated conception within 28 days after vaccination with modified vaccinia ankara bavarian nordic vector expressing multiple filovirus proteins (MVA-BN-Filo) or within 3 months after vaccination with Ad26 vector expressing the glycoprotein of the Ebola virus mayinga variant (Ad26.ZEBOV) were reported. Data of this endpoint is reported only for Cohort 3 because only Cohort 3 subjects were children. FAS included all subjects who were enrolled in this study and had at least one post baseline visit, regardless of the occurrence of protocol deviations.

End point type	Primary

End point timeframe:

Within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics was done, no inferential statistical analysis was performed.

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 3: Ad26.ZEBOV and/or MVA-BN-Filo	Cohort 3: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Children	2	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Children With Serious Adverse Events who Were 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

End point title	Number of Children With Serious Adverse Events who Were 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[4][5]

End point description:

A serious adverse event is any untoward medical occurrence that at any dose results in death, is life-threatening, 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. Data for this endpoint was reported only for Cohort 3 because only Cohort 3 had children. FAS included all subjects who were enrolled in this study and had at least one post baseline visit, regardless of the occurrence of protocol deviations.

End point type	Primary

End point timeframe:

Up to 60 months after birth

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics was done, no inferential statistical analysis was performed.

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 3: Ad26.ZEBOV and/or MVA-BN-Filo	Cohort 3: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Children	2	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Up to 60 months after dose 1 vaccination (including the duration in the subjects original study)

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo

Reporting group description:

Safety data of subjects vaccinated Ad26.ZEBOV and/or MVA-BN-Filo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003 (adults, adolescents and children) and who consented to participate in the current study was collected in 6-month intervals and up to a total of 60 months after vaccination (including the duration in the subject's original study). No vaccine was to be administered in the current study.

Reporting group title	Cohort 1: Placebo

Reporting group description:

Safety data of subjects vaccinated with Ad26.ZEBOV matching placebo and/or MVA-BN-Filo matching placebo in) in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003 (adults, adolescents and children) and who consented to participate in the current study was collected in 6-month intervals and up to a total of 60 months after vaccination (including the duration in the subject's original study). No vaccine was to be administered in the current study.

Reporting group title	Cohort 3: Ad26.ZEBOV and/or MVA-BNFilo

Reporting group description:

Safety data of children born to female subjects exposed to Ad26.ZEBOV and/or MVA-BNFilo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003, who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo or within 3 months after vaccination with Ad26.ZEBOV and for whom consent for the current study was given, was collected in 6-month intervals and up to 60 months after birth. No vaccine was to be administered in the current study.

Reporting group title	Cohort 3: Placebo

Reporting group description:

Safety data of children born to female subjects exposed to Ad26.ZEBOV matching placebo and/or MVA-BNFilo matching placebo in Phase 1, 2 or 3 clinical studies VAC52150EBL1001, VAC52150EBL1002, VAC52150EBL1003, VAC52150EBL1004, VAC52150EBL2001, VAC52150EBL2002, VAC52150EBL3002 and VAC52150EBL3003, who became pregnant with estimated conception within 28 days after vaccination with MVA-BN-Filo matching placebo or within 3 months after vaccination with Ad26.ZEBOV matching placebo and for whom consent for the current study was given, was collected in 6-month intervals and up to 60 months after birth. No vaccine was to be administered in the current study.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Only serious adverse events were planned to be collected and investigated during the study. Non-Serious adverse events were not collected, and therefore not tabulated.

Serious adverse events	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo	Cohort 1: Placebo	Cohort 3: Ad26.ZEBOV and/or MVA-BNFilo
Total subjects affected by serious adverse events			
subjects affected / exposed	49 / 614 (7.98%)	1 / 53 (1.89%)	2 / 2 (100.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from			

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid Tumour Benign			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Lymphoedema			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Appendicectomy			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Caesarean Section			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			

subjects affected / exposed	2 / 614 (0.33%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anembryonic Gestation			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Medical Device Discomfort			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Food Allergy			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Concussion			

subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral Injury			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural Haematoma			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fracture			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid Artery Dissection			

subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Venous Thrombosis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paralysis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningism			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Miller Fisher Syndrome			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensory Neuropathy			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Fibre Neuropathy			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			

subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis Ulcerative			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	3 / 614 (0.49%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Acute			
subjects affected / exposed	2 / 614 (0.33%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess Limb			
subjects affected / exposed	0 / 614 (0.00%)	1 / 53 (1.89%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Sinusitis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatitis A			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	3 / 614 (0.49%)	0 / 53 (0.00%)	2 / 2 (100.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 614 (0.00%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Tuberculosis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid Fever			

subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	1 / 614 (0.16%)	0 / 53 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 3: Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast Cancer			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parathyroid Tumour Benign			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate Cancer			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Vascular disorders			
Lymphoedema			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Appendicectomy			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Caesarean Section			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anembryonic Gestation			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Medical Device Discomfort			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Food Allergy			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			

Adenomyosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian Cyst				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asthma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Concussion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Craniocerebral Injury				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extradural Haematoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Forearm Fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head Injury				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intentional Overdose				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint Dislocation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull Fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Carotid Artery Dissection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral Venous Thrombosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervicobrachial Syndrome				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial Paralysis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningism				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Miller Fisher Syndrome				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral Sensory Neuropathy				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small Fibre Neuropathy				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Cataract				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Colitis Ulcerative				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal Ulcer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal Hernia				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis Acute			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess Limb			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic Sinusitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Covid-19				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis A				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaria				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Measles				
subjects affected / exposed	1 / 1 (100.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary Tuberculosis				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Typhoid Fever			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary Tract Infection			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral Infection			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Cohort 1: Ad26.ZEBOV and/or MVA-BN-Filo	Cohort 1: Placebo	Cohort 3: Ad26.ZEBOV and/or MVA-BNFilo
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 614 (0.00%)	0 / 53 (0.00%)	0 / 2 (0.00%)

Non-serious adverse events	Cohort 3: Placebo		
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 1 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 March 2016	Originally, all subjects who were exposed to Ad26.ZEBOV and/or MVA-BN-Filo in a Phase 1, 2 or 3 clinical study were to be approached to consent for enrollment into the VAC52150EBL4001 study. With this amendment, this was no longer be the case. Each local authority will determine which cohorts will be opened for enrollment in their region. It is not mandatory to open all cohorts for enrollment. As a result, a local authority may restrict enrollment to 1 or 2 cohorts, rather than allowing enrollment in all cohorts. The original development plan (at the time of the ongoing Ebola epidemic in Africa) was an accelerated plan with the anticipation of conducting Phase 3 efficacy studies (with limited safety data collection) shortly after Phase 1 and in parallel with Phase 2. The sponsor designed the VAC52150EBL4001 study for the extended follow-up of serious adverse events (SAEs) to enhance the ability for signal detection of rare events. Since there is no longer an ongoing Ebola epidemic, it is not currently possible to conduct a parallel Phase 3 efficacy study as part of an accelerated development plan. More controlled safety data will become available for all vaccinated subjects, therefore, prior to any potential future efficacy study.
30 September 2016	Since validated assays were not available to assess immune responses in the ongoing Phase 2 and 3 studies, unblinding of these studies had been delayed. Therefore, subjects who received placebo in their original Phase 2 or 3 study were also approached for enrollment into the VAC52150 Vaccine Development Roll-over study before unblinding of their original study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported