Clinical trial results:
A Randomized, Observer-blind, Placebo-controlled, Phase 2 Study to Evaluate the Safety, Tolerability and Immunogenicity of Different Prime-boost Regimens of the Candidate Prophylactic Vaccines for Ebola Ad26.ZEBOV and MVA-BN-Filo in Healthy Adults, Including Elderly Subjects, HIV-infected Subjects, and Healthy Children in Two Age Strata in Africa

Summary

EudraCT number	2019-000690-22
Trial protocol	Outside EU/EEA
Global end of trial date	12 February 2019

Results information

Result version number	v1 (current)
This version publication date	28 August 2019
First version publication date	28 August 2019

Trial information

Trial identification

Sponsor protocol code	CR107249

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02564523
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Vaccines & Prevention B.V.
Sponsor organisation address	Archimedesweg 29, Leiden, Netherlands, 2333 CM
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)	Yes
EMA paediatric investigation plan number(s)	EMEA-002307-PIP01-17, EMEA-002308-PIP01-17
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 February 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 February 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the safety and tolerability of different vaccination schedules of adenovirus serotype 26 expressing the Ebola virus Mayinga glycoprotein (Ad26.ZEBOV) and Modified Vaccinia Ankara Bavarian Nordic vector expressing multiple filovirus proteins (MVA-BN-Filo) administered intramuscularly (IM) as heterologous prime-boost regimens on Days 1 and 29, Days 1 and 57, or Days 1 and 85, in healthy adults, including elderly subjects, and on Days 1 and 29, or Days 1 and 57 in human immunodeficiency virus (HIV) infected subjects and healthy children in 2 age strata.

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 Practices and applicable regulatory requirements. Safety evaluations included monitoring of adverse events (AEs), serious adverse events (SAEs), solicited local and systemic adverse events (AEs), clinical laboratory parameters (chemistry, hematology, urinalysis), vital signs, electrocardiograms (ECG), and physical examination.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 November 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Burkina Faso: 369
Country: Number of subjects enrolled	Côte d'Ivoire: 178
Country: Number of subjects enrolled	Kenya: 158
Country: Number of subjects enrolled	Uganda: 368
Worldwide total number of subjects	1073
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	133
Adolescents (12-17 years)	130
Adults (18-64 years)	802
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1073 subjects were enrolled into the study. Of these, 1035 subjects completed the study and 38 subjects discontinued.

Period 1

Period 1 title	REGIMEN (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Arm description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 viral particles (vp) on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.

Arm type	Experimental
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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 viral particles) vaccine on Day 1. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 29.

Arm title	Cohort 1 (Group 1): Placebo, 28-Day Interval

Arm description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9 percent [%] saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.

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 first dose of placebo (0.5 mL IM injection of 0.9 percent [%] saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.

Arm title	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Arm description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.

Arm type	Experimental
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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 vp) vaccine on Day 1. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 57.

Arm title	Cohort 1 (Group 2): Placebo, 56-Day Interval

Arm description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.

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 one 0.5 mL IM injection of 0.9% saline on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.

Arm title	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval

Arm description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 84-day interval that is on Day 85.

Arm type	Experimental

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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 vp) vaccine on Day 1.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 85.

Arm title	Cohort 1 (Group 3): Placebo, 84-Day Interval

Arm description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 84-day interval that is on Day 85.

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 one 0.5 mL IM injection of 0.9% saline on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 84-day interval that is on Day 85.

Arm title	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Arm description:

Subjects (human immunodeficiency virus [HIV]-infected subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 29.

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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 vp) vaccine on Day 1.

Arm title	Cohort 2a: Placebo, 28-Day Interval

Arm description:

Subjects (HIV-infected subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

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 one 0.5 mL IM injection of 0.9% saline on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Arm title	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Arm description:

Subjects (HIV-infected subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 57.

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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 vp) vaccine on Day 1.

Arm title	Cohort 2a: Placebo, 56-Day Interval

Arm description:

Subjects (HIV-infected subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

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 one 0.5 mL IM injection of 0.9% saline on Day 1 followed by a second vaccination of placebo (0.9% saline) at a 56-day interval that is on Day 57.

Arm title	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Arm description:

Subjects (healthy adolescents) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Arm type	Experimental
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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 vp) vaccine on Day 1.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 29.

Arm title	Cohort 2b: Placebo, 28-Day Interval

Arm description:

Subjects (healthy adolescents) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

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 one 0.5 mL IM injection of 0.9% saline on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Arm title	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Arm description:

Subjects (healthy adolescents) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Arm type	Experimental
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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 vp) vaccine on Day 1.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 57.

Arm title	Cohort 2b: Placebo, 56-Day Interval

Arm description:

Subjects (healthy adolescents) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

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 one 0.5 mL IM injection of 0.9% saline on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Arm title	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Arm description:

Subjects (healthy children) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Arm type	Experimental
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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 vp) vaccine on Day 1.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 29.

Arm title	Cohort 3: Placebo, 28-Day Interval

Arm description:

Subjects (healthy children) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

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 one 0.5 mL IM injection of 0.9% saline on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Arm title	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Arm description:

Subjects (healthy children) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

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 one 0.5 mL IM injection of MVA-BN-Filo (1*10^8 infectious units) vaccine on Day 57.

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 one 0.5 mL IM injection of Ad26.ZEBOV (5*10^10 vp) vaccine on Day 1.

Arm title	Cohort 3: Placebo, 56-Day Interval

Arm description:

Subjects (healthy children) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

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 one 0.5 mL IM injection of 0.9% saline on Day 1 followed by a second vaccination of placebo (0.9% saline) at a 56-day interval that is on Day 57.

Number of subjects in period 1	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Started	225	43	224
Completed	215	40	214
Not completed	10	3	10
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	3	-	1
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Unspecified	3	-	-
Lost to follow-up	2	1	4
Protocol deviation	2	2	5

Number of subjects in period 1	Cohort 1 (Group 2): Placebo, 56-Day Interval	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval
Started	44	110	22
Completed	43	106	22
Not completed	1	4	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	1	-
Physician decision	-	1	-
Adverse event, non-fatal	-	-	-

Unspecified	1	-	-
Lost to follow-up	-	1	-
Protocol deviation	-	1	-

Number of subjects in period 1	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Started	59	12	59
Completed	56	12	59
Not completed	3	0	0
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	1	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Unspecified	-	-	-
Lost to follow-up	1	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-	Cohort 2b: Placebo, 28-Day Interval
Started	12	55	11
Completed	12	52	10
Not completed	0	3	1
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	-	1	-
Physician decision	-	1	-
Adverse event, non-fatal	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	1
Protocol deviation	-	-	-

Number of subjects in period 1	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval
Started	55	10	54
Completed	53	10	54
Not completed	2	0	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Unspecified	-	-	-
Lost to follow-up	1	-	-

Protocol deviation	-	-	-

Number of subjects in period 1	Cohort 3: Placebo, 28-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-	Cohort 3: Placebo, 56-Day Interval
Started	12	54	12
Completed	12	54	11
Not completed	0	0	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	1
Unspecified	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 viral particles (vp) on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.

Reporting group title	Cohort 1 (Group 1): Placebo, 28-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9 percent [%] saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.

Reporting group title	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.

Reporting group title	Cohort 1 (Group 2): Placebo, 56-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.

Reporting group title	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 84-day interval that is on Day 85.

Reporting group title	Cohort 1 (Group 3): Placebo, 84-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 84-day interval that is on Day 85.

Reporting group title	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (human immunodeficiency virus [HIV]-infected subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2a: Placebo, 28-Day Interval

Reporting group description:

Subjects (HIV-infected subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (HIV-infected subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Reporting group title	Cohort 2a: Placebo, 56-Day Interval

Reporting group description:

Subjects (HIV-infected subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Reporting group title	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2b: Placebo, 28-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Reporting group title	Cohort 2b: Placebo, 56-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Reporting group title	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Reporting group title	Cohort 3: Placebo, 28-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Reporting group title	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Reporting group title	Cohort 3: Placebo, 56-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Reporting group values	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Number of subjects	225	43	224
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	222	43	223
From 65 to 84 years	3	0	1
85 years and over	0	0	0
Title for AgeContinuous			
Units: years			
arithmetic mean	33.3	32	33.3
standard deviation	± 12.41	± 10.43	± 11.52
Title for Gender			
Units: subjects			
Female	73	15	71

Male	152	28	153

Reporting group values	Cohort 1 (Group 2): Placebo, 56-Day Interval	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval
Number of subjects	44	110	22
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	42	109	21
From 65 to 84 years	2	1	1
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	33.3	31.4	33.7
standard deviation	± 11.57	± 11.53	± 12.31
Title for Gender Units: subjects			
Female	16	27	8
Male	28	83	14

Reporting group values	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Number of subjects	59	12	59
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	59	12	59
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	38.8	34.3	39
standard deviation	± 6.61	± 7.66	± 6.69
Title for Gender Units: subjects			
Female	39	8	42
Male	20	4	17

Reporting group values	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-	Cohort 2b: Placebo, 28-Day Interval
Number of subjects	12	55	11
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	1	0
Adolescents (12-17 years)	0	54	11

Adults (18-64 years)	12	0	0
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	42.1	14.4	14.5
standard deviation	± 4.96	± 1.76	± 1.86
Title for Gender Units: subjects			
Female	10	25	5
Male	2	30	6

Reporting group values	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval
Number of subjects	55	10	54
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	54
Adolescents (12-17 years)	55	10	0
Adults (18-64 years)	0	0	0
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	14.1	14.2	7.6
standard deviation	± 1.56	± 1.81	± 2.06
Title for Gender Units: subjects			
Female	26	4	27
Male	29	6	27

Reporting group values	Cohort 3: Placebo, 28-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-	Cohort 3: Placebo, 56-Day Interval
Number of subjects	12	54	12
Title for AgeCategorical Units: subjects			
Children (2-11 years)	12	54	12
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	7.1	7.8	7.3
standard deviation	± 2.07	± 2.23	± 2.09
Title for Gender Units: subjects			
Female	5	28	5
Male	7	26	7

Reporting group values	Total		
Number of subjects	1073		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	133		
Adolescents (12-17 years)	130		
Adults (18-64 years)	802		
From 65 to 84 years	8		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		
Title for Gender Units: subjects			
Female	434		
Male	639		

End points

End points reporting groups

Reporting group title	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval
Reporting group description:	
Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 viral particles (vp) on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.	
Reporting group title	Cohort 1 (Group 1): Placebo, 28-Day Interval
Reporting group description:	
Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9 percent [%] saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.	
Reporting group title	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Reporting group description:	
Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.	
Reporting group title	Cohort 1 (Group 2): Placebo, 56-Day Interval
Reporting group description:	
Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.	
Reporting group title	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval
Reporting group description:	
Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 84-day interval that is on Day 85.	
Reporting group title	Cohort 1 (Group 3): Placebo, 84-Day Interval
Reporting group description:	
Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 84-day interval that is on Day 85.	
Reporting group title	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval
Reporting group description:	
Subjects (human immunodeficiency virus [HIV]-infected subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.	
Reporting group title	Cohort 2a: Placebo, 28-Day Interval
Reporting group description:	
Subjects (HIV-infected subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.	
Reporting group title	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Reporting group description:	
Subjects (HIV-infected subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.	
Reporting group title	Cohort 2a: Placebo, 56-Day Interval
Reporting group description:	
Subjects (HIV-infected subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.	
Reporting group title	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2b: Placebo, 28-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Reporting group title	Cohort 2b: Placebo, 56-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Reporting group title	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Reporting group title	Cohort 3: Placebo, 28-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Reporting group title	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Reporting group title	Cohort 3: Placebo, 56-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Primary: Number of Subjects with Unsolicited Adverse Events (Post-dose 1 and Post-dose 2 combined)

End point title	Number of Subjects with Unsolicited Adverse Events (Post-dose 1 and Post-dose 2 combined)[1]

End point description:

An Adverse Events (AEs) is any untoward medical event that occurs in a subject administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. Unsolicited AEs included all AEs for which the subject was specifically not questioned in the subject diary. The full analysis set (FAS) included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations (PDs).

End point type	Primary

End point timeframe:

Up to Day 113 (28 days post-dose 1 and post-dose 2)

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 were done, no inferential statistical analyses were performed.

End point values	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 1 (Group 2): Placebo, 56-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	225	43	224	44
Units: Subjects	126	24	100	25

End point values	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	22	59	12
Units: Subjects	56	13	35	9

End point values	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2b: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	12	55	11
Units: Subjects	33	5	35	5

End point values	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 3: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	10	54	12
Units: Subjects	42	6	34	9

End point values	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 3: Placebo, 56-Day Interval		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	12		
Units: Subjects	30	9		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Serious Adverse Events

End point title	Number of Subjects with Serious Adverse Events[2]

End point description:

An SAE is any AE that results in: death, persistent or significant disability/incapacity, requires inpatient hospitalization or prolongation of existing hospitalization, is life-threatening experience, is a congenital anomaly/birth defect and may jeopardize subjects and/or may require medical or surgical intervention to prevent one of the outcomes listed above. The FAS included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of PDs.

End point type	Primary

End point timeframe:

Up to Day 720 (from signing of informed consent form up to end of study)

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 were done, no inferential statistical analyses were performed.

End point values	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 1 (Group 2): Placebo, 56-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	225	43	224	44
Units: Subjects	7	1	7	0

End point values	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	22	59	12
Units: Subjects	6	0	1	0

End point values	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2b: Placebo, 28-Day Interval

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	12	55	11
Units: Subjects	1	0	1	0

End point values	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 3: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	10	54	12
Units: Subjects	0	0	1	0

End point values	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 3: Placebo, 56-Day Interval		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	12		
Units: Subjects	0	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Immediate Reportable Event (IRE)

End point title	Number of Subjects with Immediate Reportable Event (IRE)[3]

End point description:

Number of subjects with IREs were reported. IRE: Any event of neuroimmunologic significance. FAS included all subjects who were randomized and received at least 1 dose of study vaccine, regardless of occurrence of PDs.

End point type	Primary

End point timeframe:

Up to Day 720 (from signing of Informed Consent Form up to end of study)

Notes:

[3] - 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 were done, no inferential statistical analyses were performed.

End point values	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 1 (Group 2): Placebo, 56-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	225	43	224	44
Units: Subjects	0	0	0	0

End point values	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	22	59	12
Units: Subjects	0	0	0	0

End point values	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2b: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	12	55	11
Units: Subjects	0	0	0	0

End point values	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 3: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	10	54	12
Units: Subjects	0	0	0	0

End point values	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 3: Placebo, 56-Day Interval		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	12		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Solicited Local and Systemic Adverse Events (Post-dose 1 and Post-dose 2 Combined)

End point title	Number of Subjects with Solicited Local and Systemic Adverse Events (Post-dose 1 and Post-dose 2 Combined)[4]

End point description:

Number of subjects with solicited injection site (local and systemic) AEs were reported. Solicited local AEs (pain, erythema, and induration at the study vaccine injection site) and systemic AEs (fever, chills, headache, fatigue, nausea, myalgia, and arthralgia) were noted in the subject diary until 7 days after each administration of study vaccine. The FAS included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of PDs.

End point type	Primary

End point timeframe:

Up to Day 92 (7 days post-dose 1 and post-dose 2)

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 were done, no inferential statistical analyses were performed.

End point values	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 1 (Group 2): Placebo, 56-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	225	43	224	44
Units: Subjects				
Solicited Local AE	154	19	155	23
Solicited Systemic AE	165	29	171	28

End point values	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	22	59	12
Units: Subjects				
Solicited Local AE	81	12	40	5
Solicited Systemic AE	90	17	49	7

End point values	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2b: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	12	55	11
Units: Subjects				
Solicited Local AE	40	2	35	5
Solicited Systemic AE	40	7	34	4

End point values	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 3: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	10	54	12
Units: Subjects				
Solicited Local AE	33	5	34	6
Solicited Systemic AE	34	6	26	3

End point values	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 3: Placebo, 56-Day Interval		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	12		
Units: Subjects				
Solicited Local AE	33	5		
Solicited Systemic AE	24	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Anti-Ebola virus (EBOV) Glycoprotein (GP) Binding Antibodies Level

End point title	Percentage of Subjects with Anti-Ebola virus (EBOV) Glycoprotein (GP) Binding Antibodies Level

End point description:

Percentage of subjects with anti-EBOV GP binding antibodies levels elicited by vaccination by enzyme-linked immunosorbent assay (ELISA) were reported. The per protocol analysis set included all randomized and vaccinated subjects, who received both the prime and boost (administered not more than 10 days outside the visit window) vaccinations, had immunogenicity data from baseline and at least one post-vaccination evaluable immunogenicity sample, and had no major protocol violations influencing the immune response. 99999 indicates that data was not assessable as no subject was analysed for this endpoint at specified timepoint.

End point type	Secondary

End point timeframe:

Day 50, Day 78, and Day 106

End point values	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 1 (Group 2): Placebo, 56-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	169	32	134	24
Units: Percentage of Subjects				
number (not applicable)				
Day 50	100	13.3	99999	99999
Day 78	99999	99999	100	33.3
Day 106	99999	99999	99999	99999

End point values	Cohort 1 (Group 3):Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	7	58	10
Units: Percentage of Subjects				
number (not applicable)				
Day 50	99999	99999	100	36.4
Day 78	99999	99999	99999	99999
Day 106	100	0.0	99999	99999

End point values	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2b: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	12	54	10
Units: Percentage of Subjects				
number (not applicable)				
Day 50	99999	99999	100	30.0
Day 78	100	8.3	99999	99999
Day 106	99999	99999	99999	99999

End point values	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 3: Placebo, 28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	10	53	12
Units: Percentage of Subjects				

number (not applicable)				
Day 50	99999	99999	100	25.0
Day 78	100	30.0	99999	99999
Day 106	99999	99999	99999	99999

End point values	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 3: Placebo, 56-Day Interval		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	11		
Units: Percentage of Subjects				
number (not applicable)				
Day 50	99999	99999		
Day 78	100	9.1		
Day 106	99999	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1 Substudy: Number of Subjects with Unsolicited Adverse Events (Post booster dose)

End point title	Cohort 1 Substudy: Number of Subjects with Unsolicited Adverse Events (Post booster dose)[5]

End point description:

An AE is any untoward medical event that occurs in a subject administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. Unsolicited AEs included all AEs for which the subject was specifically not questioned in the subject diary. The FAS included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of PDs. Here 'N' (number of subjects analysed) signifies those subjects who were evaluable for this endpoint. This endpoint was planned to be analysed and reported for specified cohorts only.

End point type	Secondary

End point timeframe:

Up to Day 393 (28 days post booster dose [dose 3])

Notes:

[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 analysed for specified arms only.

End point values	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 1 (Group 2): Placebo, 56-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	8	39	9
Units: Subjects	9	3	14	0

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1 Substudy: Number of Subjects with Solicited Local and Systemic Adverse Events (Post booster dose)

End point title	Cohort 1 Substudy: Number of Subjects with Solicited Local and Systemic Adverse Events (Post booster dose)[6]

End point description:

Number of subjects with solicited injection site (local and systemic) AEs were reported. Solicited local AEs (pain, erythema, and induration at the study vaccine injection site) and systemic AEs (fever, chills, headache, fatigue, nausea, myalgia, and arthralgia) were noted in the subject diary until 7 days after each administration of study vaccine. Here 'N' (number of subjects analysed) signifies those subjects who were evaluable for this endpoint. Here 'N' (number of subjects analysed) signifies those subjects who were evaluable for this endpoint. This endpoint was planned to be analysed and reported for specified cohorts only.

End point type	Secondary

End point timeframe:

Up to Day 372 (7 days post booster dose [dose 3])

Notes:

[6] - 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 analysed for specified arms only.

End point values	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1(Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 1 (Group 2): Placebo, 56-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	8	34	9
Units: Subjects				
Solicited Local AE	18	1	16	3
Solicited Systemic AE	17	2	18	4

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Day 720

Adverse event reporting additional description:

The full analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo,28-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 viral particles (vp) on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.

Reporting group title	Cohort 1 (Group 1): Placebo, 28-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9 percent [%] saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.

Reporting group title	Cohort 1 (Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of Ad26.ZEBOV (5*10^10 vp) on Day 365.

Reporting group title	Cohort 1 (Group 2): Placebo, 56-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57. Only subjects who reconsented for sub-study received a booster dose of placebo on Day 365.

Reporting group title	Cohort 1(Group 3): Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 84-day interval that is on Day 85.

Reporting group title	Cohort 1 (Group 3): Placebo, 84-Day Interval

Reporting group description:

Subjects (healthy adult and elderly subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 84-day interval that is on Day 85.

Reporting group title	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (human immunodeficiency virus [HIV]-infected subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2a: Placebo, 28-Day Interval

Reporting group description:

Subjects (HIV-infected subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (HIV-infected subjects) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Reporting group title	Cohort 2a: Placebo, 56-Day Interval

Reporting group description:

Subjects (HIV-infected subjects) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Reporting group title	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2b: Placebo, 28-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Reporting group title	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Reporting group title	Cohort 2b: Placebo, 56-Day Interval

Reporting group description:

Subjects (healthy adolescents) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Reporting group title	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 28-day interval that is on Day 29.

Reporting group title	Cohort 3: Placebo, 28-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 28-day interval that is on Day 29.

Reporting group title	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of Ad26.ZEBOV vaccine at a dose of 5*10^10 vp on Day 1, followed by a second vaccination using MVA-BN-Filo at a dose of 1*10^8 infectious units at a 56-day interval that is on Day 57.

Reporting group title	Cohort 3: Placebo, 56-Day Interval

Reporting group description:

Subjects (healthy children) received first dose of placebo (0.9% saline) on Day 1 followed by a second vaccination using placebo (0.9% saline) at a 56-day interval that is on Day 57.

Serious adverse events	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo,28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1 (Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 225 (3.11%)	1 / 43 (2.33%)	7 / 224 (3.13%)
number of deaths (all causes)	0	0	0
number of deaths resulting from			

adverse events			
Injury, poisoning and procedural complications			
Alcohol Poisoning			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (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
Burns Second Degree			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (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
Ligament Sprain			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (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
Congenital, familial and genetic disorders			
Dolichocolon			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (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	1 / 225 (0.44%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anembryonic Gestation			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (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
Ear and labyrinth disorders			
Meniere's Disease			
subjects affected / exposed	0 / 225 (0.00%)	1 / 43 (2.33%)	0 / 224 (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
Eye disorders			

Cataract			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (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			
Inguinal Hernia			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction Gastric			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (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
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (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	1 / 225 (0.44%)	1 / 43 (2.33%)	3 / 224 (1.34%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (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
Typhoid Fever			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (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
Metabolism and nutrition disorders			
Electrolyte Imbalance			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 1 (Group 2): Placebo, 56-Day Interval	Cohort 1(Group 3): Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 44 (0.00%)	6 / 110 (5.45%)	0 / 22 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Alcohol Poisoning			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Burns Second Degree			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Ligament Sprain			

subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Congenital, familial and genetic disorders			
Dolichocolon			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Anembryonic Gestation			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (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
Ear and labyrinth disorders			
Meniere's Disease			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Glaucoma			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Gastrointestinal disorders			
Inguinal Hernia			

subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (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
Obstruction Gastric			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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
Malaria			
subjects affected / exposed	0 / 44 (0.00%)	3 / 110 (2.73%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (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
Typhoid Fever			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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

Metabolism and nutrition disorders			
Electrolyte Imbalance			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (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

Serious adverse events	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	1 / 59 (1.69%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Alcohol Poisoning			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Burns Second Degree			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Ligament Sprain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Congenital, familial and genetic disorders			
Dolichocolon			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			

subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Anembryonic Gestation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Ear and labyrinth disorders			
Meniere's Disease			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Glaucoma			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Gastrointestinal disorders			
Inguinal Hernia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Obstruction Gastric			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Malaria			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Typhoid Fever			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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
Metabolism and nutrition disorders			
Electrolyte Imbalance			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (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

Serious adverse events	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-	Cohort 2b: Placebo, 28-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)

number of deaths (all causes) number of deaths resulting from adverse events	0	1	0
Injury, poisoning and procedural complications			
Alcohol Poisoning			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Burns Second Degree			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Ligament Sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Congenital, familial and genetic disorders			
Dolichocolon			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Anembryonic Gestation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Ear and labyrinth disorders			
Meniere's Disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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

Eye disorders			
Cataract			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Glaucoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Gastrointestinal disorders			
Inguinal Hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Obstruction Gastric			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Malaria			

subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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
Typhoid Fever			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metabolism and nutrition disorders			
Electrolyte Imbalance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (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

Serious adverse events	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	1 / 54 (1.85%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Alcohol Poisoning			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Burns Second Degree			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Ligament Sprain			

subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Congenital, familial and genetic disorders			
Dolichocolon			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Anembryonic Gestation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Ear and labyrinth disorders			
Meniere's Disease			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Glaucoma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Gastrointestinal disorders			
Inguinal Hernia			

subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Obstruction Gastric			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Malaria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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
Typhoid Fever			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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

Metabolism and nutrition disorders			
Electrolyte Imbalance			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (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

Serious adverse events	Cohort 3: Placebo, 28-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-	Cohort 3: Placebo, 56-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 12 (8.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Alcohol Poisoning			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Burns Second Degree			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Congenital, familial and genetic disorders			
Dolichocolon			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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

Anembryonic Gestation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Ear and labyrinth disorders			
Meniere's Disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Glaucoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Gastrointestinal disorders			
Inguinal Hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Obstruction Gastric			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Renal and urinary disorders			
Acute Kidney Injury			

subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Malaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Typhoid Fever			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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
Metabolism and nutrition disorders			
Electrolyte Imbalance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (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

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Cohort 1(Group 1):Ad26.ZEBOV and MVA-BN-Filo,28-Day Interval	Cohort 1 (Group 1): Placebo, 28-Day Interval	Cohort 1 (Group 2):Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	94 / 225 (41.78%)	17 / 43 (39.53%)	80 / 224 (35.71%)
General disorders and administration site conditions			

Chest Pain			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	2 / 224 (0.89%)
occurrences (all)	1	0	2
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	3 / 225 (1.33%)	1 / 43 (2.33%)	1 / 224 (0.45%)
occurrences (all)	3	1	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 225 (0.44%)	2 / 43 (4.65%)	4 / 224 (1.79%)
occurrences (all)	1	2	4
Productive Cough			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences (all)	0	0	1
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 225 (0.00%)	1 / 43 (2.33%)	1 / 224 (0.45%)
occurrences (all)	0	1	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	2 / 225 (0.89%)	2 / 43 (4.65%)	2 / 224 (0.89%)
occurrences (all)	2	2	2
Blood Potassium Decreased			
subjects affected / exposed	2 / 225 (0.89%)	0 / 43 (0.00%)	3 / 224 (1.34%)
occurrences (all)	2	0	3
Blood Pressure Increased			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	9 / 225 (4.00%)	0 / 43 (0.00%)	4 / 224 (1.79%)
occurrences (all)	9	0	4
Blood Urea Decreased			

subjects affected / exposed	3 / 225 (1.33%)	0 / 43 (0.00%)	2 / 224 (0.89%)
occurrences (all)	4	0	2
Monocyte Count Decreased			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences (all)	1	0	1
Transaminases Increased			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	15 / 225 (6.67%)	4 / 43 (9.30%)	8 / 224 (3.57%)
occurrences (all)	15	4	8
Paraesthesia			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	1 / 224 (0.45%)
occurrences (all)	1	0	1

Leukopenia			
subjects affected / exposed	1 / 225 (0.44%)	1 / 43 (2.33%)	4 / 224 (1.79%)
occurrences (all)	1	1	4
Microcytic Anaemia			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	14 / 225 (6.22%)	1 / 43 (2.33%)	8 / 224 (3.57%)
occurrences (all)	14	1	9
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis Allergic			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	1	0	0
Eye Pruritus			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal Pain Lower			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
subjects affected / exposed	2 / 225 (0.89%)	1 / 43 (2.33%)	2 / 224 (0.89%)
occurrences (all)	2	1	2
Diarrhoea			
subjects affected / exposed	3 / 225 (1.33%)	0 / 43 (0.00%)	3 / 224 (1.34%)
occurrences (all)	3	0	3
Food Poisoning			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue			

disorders			
Back Pain			
subjects affected / exposed	3 / 225 (1.33%)	1 / 43 (2.33%)	5 / 224 (2.23%)
occurrences (all)	3	1	5
Myalgia			
subjects affected / exposed	5 / 225 (2.22%)	0 / 43 (0.00%)	5 / 224 (2.23%)
occurrences (all)	5	0	5
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 225 (1.33%)	2 / 43 (4.65%)	4 / 224 (1.79%)
occurrences (all)	3	2	4
Conjunctivitis			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	2 / 224 (0.89%)
occurrences (all)	1	0	2
Infection Parasitic			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	2 / 225 (0.89%)	1 / 43 (2.33%)	4 / 224 (1.79%)
occurrences (all)	2	1	5
Malaria			
subjects affected / exposed	16 / 225 (7.11%)	2 / 43 (4.65%)	12 / 224 (5.36%)
occurrences (all)	16	2	14
Nasopharyngitis			
subjects affected / exposed	8 / 225 (3.56%)	4 / 43 (9.30%)	11 / 224 (4.91%)
occurrences (all)	8	4	11
Pharyngitis			
subjects affected / exposed	2 / 225 (0.89%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	2	0	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 225 (0.00%)	1 / 43 (2.33%)	1 / 224 (0.45%)
occurrences (all)	0	1	1
Rhinitis			
subjects affected / exposed	7 / 225 (3.11%)	0 / 43 (0.00%)	2 / 224 (0.89%)
occurrences (all)	7	0	2
Sepsis			

subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	3 / 225 (1.33%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	3	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	17 / 225 (7.56%)	1 / 43 (2.33%)	18 / 224 (8.04%)
occurrences (all)	20	1	18
Vulvovaginal Candidiasis			
subjects affected / exposed	1 / 225 (0.44%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypercreatininaemia			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	2 / 225 (0.89%)	2 / 43 (4.65%)	0 / 224 (0.00%)
occurrences (all)	2	2	0
Hypokalaemia			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 225 (0.00%)	0 / 43 (0.00%)	0 / 224 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 1 (Group 2): Placebo, 56-Day Interval	Cohort 1(Group 3): Ad26.ZEBOV and MVA-BN-Filo, 84-Day Interval	Cohort 1 (Group 3): Placebo, 84-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 44 (47.73%)	43 / 110 (39.09%)	12 / 22 (54.55%)
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	1 / 44 (2.27%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Hypersensitivity			

subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	3 / 44 (6.82%)	2 / 110 (1.82%)	0 / 22 (0.00%)
occurrences (all)	3	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Productive Cough			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Blood Potassium Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Urea Decreased			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Monocyte Count Decreased			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0

Neutrophil Count Decreased			
subjects affected / exposed	1 / 44 (2.27%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Transaminases Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 44 (6.82%)	7 / 110 (6.36%)	2 / 22 (9.09%)
occurrences (all)	3	7	3
Paraesthesia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Microcytic Anaemia			

subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	4 / 44 (9.09%)	2 / 110 (1.82%)	2 / 22 (9.09%)
occurrences (all)	5	2	2
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye Pruritus			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Lower			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
subjects affected / exposed	1 / 44 (2.27%)	0 / 110 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Diarrhoea			
subjects affected / exposed	1 / 44 (2.27%)	3 / 110 (2.73%)	1 / 22 (4.55%)
occurrences (all)	1	3	1
Food Poisoning			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	3 / 44 (6.82%)	3 / 110 (2.73%)	0 / 22 (0.00%)
occurrences (all)	3	4	0

Myalgia			
subjects affected / exposed	0 / 44 (0.00%)	2 / 110 (1.82%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 44 (0.00%)	3 / 110 (2.73%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
Infection Parasitic			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 44 (2.27%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Malaria			
subjects affected / exposed	5 / 44 (11.36%)	6 / 110 (5.45%)	2 / 22 (9.09%)
occurrences (all)	6	6	2
Nasopharyngitis			
subjects affected / exposed	1 / 44 (2.27%)	2 / 110 (1.82%)	1 / 22 (4.55%)
occurrences (all)	1	3	1
Pharyngitis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 44 (2.27%)	4 / 110 (3.64%)	2 / 22 (9.09%)
occurrences (all)	1	4	2
Sepsis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			

subjects affected / exposed	1 / 44 (2.27%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 44 (6.82%)	9 / 110 (8.18%)	3 / 22 (13.64%)
occurrences (all)	3	9	3
Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hypercreatininaemia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			
subjects affected / exposed	0 / 44 (0.00%)	2 / 110 (1.82%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
Hypokalaemia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 110 (0.91%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 110 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval	Cohort 2a: Placebo, 28-Day Interval	Cohort 2a: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 59 (40.68%)	9 / 12 (75.00%)	28 / 59 (47.46%)
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Menorrhagia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	2 / 59 (3.39%)
occurrences (all)	0	0	2
Productive Cough			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	4 / 59 (6.78%)
occurrences (all)	0	1	4
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	2 / 59 (3.39%)
occurrences (all)	0	0	2
Blood Potassium Decreased			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Blood Pressure Increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Blood Sodium Decreased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Blood Urea Decreased			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
Monocyte Count Decreased			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Transaminases Increased			

subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Ligament Sprain			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 59 (5.08%)	0 / 12 (0.00%)	2 / 59 (3.39%)
occurrences (all)	4	0	2
Paraesthesia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	1 / 59 (1.69%)
occurrences (all)	0	1	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
Leukopenia			
subjects affected / exposed	1 / 59 (1.69%)	1 / 12 (8.33%)	3 / 59 (5.08%)
occurrences (all)	1	1	3
Microcytic Anaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 59 (3.39%)	2 / 12 (16.67%)	6 / 59 (10.17%)
occurrences (all)	2	2	6

Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Eye Pruritus			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Lower			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Dental Caries			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Food Poisoning			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	5 / 59 (8.47%)
occurrences (all)	1	0	6
Myalgia			
subjects affected / exposed	3 / 59 (5.08%)	1 / 12 (8.33%)	1 / 59 (1.69%)
occurrences (all)	3	1	1
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
Infection Parasitic			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
Malaria			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	3 / 59 (5.08%)
occurrences (all)	1	0	3
Nasopharyngitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	2 / 59 (3.39%)
occurrences (all)	0	0	2
Sepsis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	2 / 59 (3.39%)
occurrences (all)	1	0	2
Tonsillitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	7 / 59 (11.86%)	1 / 12 (8.33%)	3 / 59 (5.08%)
occurrences (all)	7	1	5

Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 12 (8.33%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hypercreatininaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	3 / 59 (5.08%)	0 / 12 (0.00%)	0 / 59 (0.00%)
occurrences (all)	3	0	0
Hypokalaemia			
subjects affected / exposed	2 / 59 (3.39%)	0 / 12 (0.00%)	3 / 59 (5.08%)
occurrences (all)	2	0	3
Hyponatraemia			
subjects affected / exposed	1 / 59 (1.69%)	1 / 12 (8.33%)	1 / 59 (1.69%)
occurrences (all)	1	1	1

Non-serious adverse events	Cohort 2a: Placebo, 56-Day Interval	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 28-	Cohort 2b: Placebo, 28-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 12 (41.67%)	29 / 55 (52.73%)	5 / 11 (45.45%)
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 12 (8.33%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	1 / 11 (9.09%)
occurrences (all)	0	1	1

Productive Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Blood Potassium Decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Blood Sodium Decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Blood Urea Decreased			
subjects affected / exposed	0 / 12 (0.00%)	5 / 55 (9.09%)	0 / 11 (0.00%)
occurrences (all)	0	5	0
Monocyte Count Decreased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Neutrophil Count Decreased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 55 (3.64%)	0 / 11 (0.00%)
occurrences (all)	1	2	0
Transaminases Increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 12 (8.33%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Paraesthesia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Microcytic Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 55 (3.64%)	0 / 11 (0.00%)
occurrences (all)	1	2	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Conjunctivitis Allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Eye Pruritus			

subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Lower			
subjects affected / exposed	1 / 12 (8.33%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Dental Caries			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Food Poisoning			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infection Parasitic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Malaria			
subjects affected / exposed	0 / 12 (0.00%)	3 / 55 (5.45%)	1 / 11 (9.09%)
occurrences (all)	0	4	1
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	3 / 55 (5.45%)	0 / 11 (0.00%)
occurrences (all)	0	3	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 55 (1.82%)	0 / 11 (0.00%)
occurrences (all)	2	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 12 (8.33%)	6 / 55 (10.91%)	0 / 11 (0.00%)
occurrences (all)	1	7	0
Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercreatininaemia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 55 (3.64%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
Hypernatraemia			

subjects affected / exposed	0 / 12 (0.00%)	6 / 55 (10.91%)	1 / 11 (9.09%)
occurrences (all)	0	6	2
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 55 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 2b: Ad26.ZEBOV and MVA-BN-Filo, 56-Day Interval	Cohort 2b: Placebo, 56-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 28-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 55 (60.00%)	6 / 10 (60.00%)	27 / 54 (50.00%)
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	1 / 55 (1.82%)	1 / 10 (10.00%)	0 / 54 (0.00%)
occurrences (all)	1	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 55 (0.00%)	1 / 10 (10.00%)	2 / 54 (3.70%)
occurrences (all)	0	1	2
Productive Cough			
subjects affected / exposed	1 / 55 (1.82%)	0 / 10 (0.00%)	3 / 54 (5.56%)
occurrences (all)	1	0	3
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 10 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Blood Potassium Decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	3 / 55 (5.45%)	1 / 10 (10.00%)	0 / 54 (0.00%)
occurrences (all)	3	1	0
Blood Urea Decreased			
subjects affected / exposed	1 / 55 (1.82%)	1 / 10 (10.00%)	0 / 54 (0.00%)
occurrences (all)	1	1	0
Monocyte Count Decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Transaminases Increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 55 (0.00%)	1 / 10 (10.00%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			

Headache			
subjects affected / exposed	4 / 55 (7.27%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	4	0	0
Paraesthesia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 10 (0.00%)	3 / 54 (5.56%)
occurrences (all)	1	0	3
Leukopenia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	2 / 54 (3.70%)
occurrences (all)	0	0	2
Microcytic Anaemia			
subjects affected / exposed	0 / 55 (0.00%)	1 / 10 (10.00%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	3 / 55 (5.45%)	1 / 10 (10.00%)	1 / 54 (1.85%)
occurrences (all)	3	1	1
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 55 (0.00%)	1 / 10 (10.00%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Eye Pruritus			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Lower			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Dental Caries			

subjects affected / exposed	1 / 55 (1.82%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 55 (0.00%)	1 / 10 (10.00%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Food Poisoning			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	4 / 54 (7.41%)
occurrences (all)	0	0	4
Conjunctivitis			
subjects affected / exposed	3 / 55 (5.45%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	4	0	0
Infection Parasitic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 55 (1.82%)	0 / 10 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Malaria			
subjects affected / exposed	8 / 55 (14.55%)	1 / 10 (10.00%)	7 / 54 (12.96%)
occurrences (all)	8	1	10
Nasopharyngitis			

subjects affected / exposed	4 / 55 (7.27%)	2 / 10 (20.00%)	1 / 54 (1.85%)
occurrences (all)	5	3	1
Pharyngitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	4 / 54 (7.41%)
occurrences (all)	0	0	4
Sepsis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 10 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 55 (5.45%)	2 / 10 (20.00%)	0 / 54 (0.00%)
occurrences (all)	3	2	0
Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercreatininaemia			
subjects affected / exposed	5 / 55 (9.09%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	5	0	0
Hypernatraemia			
subjects affected / exposed	7 / 55 (12.73%)	0 / 10 (0.00%)	4 / 54 (7.41%)
occurrences (all)	13	0	4
Hypokalaemia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 10 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 10 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1

Non-serious adverse events	Cohort 3: Placebo, 28-Day Interval	Cohort 3: Ad26.ZEBOV and MVA-BN-Filo, 56-	Cohort 3: Placebo, 56-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 12 (75.00%)	22 / 54 (40.74%)	9 / 12 (75.00%)
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 12 (25.00%)	2 / 54 (3.70%)	1 / 12 (8.33%)
occurrences (all)	3	2	1
Productive Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood Potassium Decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood Urea Decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Monocyte Count Decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Transaminases Increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 54 (1.85%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Microcytic Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 54 (1.85%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal Pain Lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
subjects affected / exposed	1 / 12 (8.33%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Food Poisoning			

subjects affected / exposed	1 / 12 (8.33%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 12 (8.33%)	2 / 54 (3.70%)	2 / 12 (16.67%)
occurrences (all)	1	2	2
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infection Parasitic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	1 / 12 (8.33%)	3 / 54 (5.56%)	0 / 12 (0.00%)
occurrences (all)	1	3	0
Malaria			
subjects affected / exposed	2 / 12 (16.67%)	4 / 54 (7.41%)	0 / 12 (0.00%)
occurrences (all)	2	4	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 54 (3.70%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	6 / 54 (11.11%)	1 / 12 (8.33%)
occurrences (all)	0	6	1
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 12 (8.33%)	4 / 54 (7.41%)	0 / 12 (0.00%)
occurrences (all)	1	4	0
Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercreatininaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	1 / 12 (8.33%)	3 / 54 (5.56%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 September 2016	The overall reason for the amendment #2 was to include the request of the Center for Biologics Evaluation and Research (CBER, a division of United States [US] Food and Drug Administration [FDA]) to change the age ranges of Cohorts 3 and 4 and to extend the safety follow-up to 6 months post-boost.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
28 April 2016	On 28 April 2016, sites were notified to halt all vaccinations due to occurrence of a serious adverse event (SAE) in VAC52150EBL2001 that met study pause rule. On 19 May 2016, when the study pause was still in a effect, a second SAE report was received for VAC52150EBL2001 and a clinical hold was issued by the FDA on 26 May 2016 on all screening and vaccinations. After receipt of follow up information, the clinical hold was lifted on 16 June 2016.	12 August 2016

Notes:

Limitations and caveats

None reported