Clinical trial results:
Partnership for Research on Ebola VACcinations

Summary

EudraCT number	2017-001798-18
Trial protocol	Outside EU/EEA
Global end of trial date	

Results information

Result version number	v1
This version publication date	06 March 2024
First version publication date	06 March 2024

Trial information

Trial identification

Sponsor protocol code	C15-33

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02876328
WHO universal trial number (UTN)	-
Other trial identifiers	PACTR: PACTR201712002760250, London School of Hygiene & Tropical Medicine: PREVACEBL3005, Merck Sharp & Dohme, Corp.: V920-016, Janssen Vaccines & Prevention B.V.: VAC52150EBL2004

Notes:

Sponsors

Sponsor organisation name	Inserm
Sponsor organisation address	101, rue de Tolbiac, Paris, France, 75654 Cedex 13
Public contact	Hélène Espérou, Inserm, +33 144 23 6070, Helene.esperou@inserm.fr
Scientific contact	Hélène Espérou, Inserm, +33 144 23 6070, Helene.esperou@inserm.fr

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001786-PIP01-15, EMEA-002307-PIP01-17, EMEA-002308-PIP01-17
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	28 June 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 December 2019
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

Antibody response 12 months after randomization

Protection of trial subjects:

Measures to minimize the risks to research participants and staff involved are:
- Thorough training of the staff
- Availability of 29 SOPs for the conduct of the clinical trial

All the staff was trained on general aspect of the clinical training such as the protocol and good clinical practice for example. Other trainings were specific to the role of the staff in the project such as laboratory activities, pharmacy activities, etc.
Health aspects were also taught to the staff, such as reanimation gesture, HIV counselling, etc.
Regarding the SOPs, they cover aspects such as general aspects of the clinical trial (randomisation, onsite document archiving, etc.), vaccination and follow-up activities (consent forms, follow-up visits, etc.), pharmacy activities, laboratory activities, data management and safety.

The Data and Safety Monitoring Board met frequently to assess the overall safety of study participants.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 March 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Guinea: 2327
Country: Number of subjects enrolled	Liberia: 1133
Country: Number of subjects enrolled	Mali: 708
Country: Number of subjects enrolled	Sierra Leone: 618
Worldwide total number of subjects	4786
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)	92
Children (2-11 years)	1207
Adolescents (12-17 years)	929
Adults (18-64 years)	2501
From 65 to 84 years	57
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Healthy volunteers enrolled in Guinea (2 sites: Landreah and Maferinyah), Liberia (Redemption Hospital), Mali (2 sites: Center for Vaccine Development and University Clinical Research Center) and Sierra Leone (Mambolo). Only data of protocol version 4.0 participants are included in the immunological analysis.

Pre-assignment

Screening details:

4789 participants were enrolled in the study, however, only 4786 participants are part of the data analysis.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	Zabdeno
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL at a dose of 5x10^10 viral particles in the arm-deltoid region or the thigh for young children Administered the day of enrollment/randomization

Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	Mvabea
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL at a dose of 5x10^10 viral particles in the arm-deltoid region or the thigh for young children Administered 56 days after Ad26.ZEBOV with a window of -3,+10 days i.e. 53 to 66 days after Ad26.ZEBOV

Arm title	Placebo 0.5 mL (prime + boost; adults)

Arm description: -

Arm type	Placebo
Investigational medicinal product name	NaCl 0.9%
Investigational medicinal product code	
Other name	Sodium chloride, saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL of 0.9% NaCl in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization and 56 days after with a window of -3,+10 days i.e.

53 to 66 days after first injection

Arm title	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	rVSVΔG-ZEBOV-GP
Investigational medicinal product code	
Other name	Ervebo
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

For participants of the protocol v3.0: 1 mL at a dose at a labelled dose of ≥7.2 x 10^7 pfu/mL (with release specifications from 7.8x10^7 pfu/mL to 2.3x10^8 pfu/mL) in the arm-deltoid region or the thigh for young children after a 2-fold dilution in 0.9% saline
For participants of the protocol v4.0: 1 mL at a dose at a labelled dose of ≥7.2 x 10^7 pfu/mL (with release specifications from 7.8x10^7 pfu/mL to 2.3x10^8 pfu/mL) in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization

Investigational medicinal product name	NaCl 0.9%
Investigational medicinal product code	
Other name	Sodium chloride, saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL of 0.9% NaCl in the arm-deltoid region or the thigh for young children
Administered 56 days after rVSVΔG-ZEBOV-GP with a window of -3,+10 days i.e. 53 to 66 days after first injection

Arm title	rVSVΔG-ZEBOV-GP (prime + boost; adults)
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	rVSVΔG-ZEBOV-GP
Investigational medicinal product code	
Other name	Ervebo
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

For participants of the protocol v3.0: 1 mL at a dose at a labelled dose of ≥7.2 x 10^7 pfu/mL (with release specifications from 7.8x10^7 pfu/mL to 2.3x10^8 pfu/mL) in the arm-deltoid region or the thigh for young children after a 2-fold dilution in 0.9% saline
For participants of the protocol v4.0: 1 mL at a dose at a labelled dose of ≥7.2 x 10^7 pfu/mL (with release specifications from 7.8x10^7 pfu/mL to 2.3x10^8 pfu/mL) in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization and 56 days after with a window of -3,+10 days i.e. 53 to 66 days after first injection

Arm title	Placebo 1 mL (prime + boost; adults)
Arm description: -	
Arm type	Placebo

Investigational medicinal product name	NaCl 0.9%
Investigational medicinal product code	
Other name	Sodium chloride, saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 mL of 0.9% NaCl in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization and 56 days after with a window of -3,+10 days i.e. 53 to 66 days after first injection

Arm title	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)

Arm description: -

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

Dosage and administration details:

0.5 mL at a dose of 5x10^10 viral particles in the arm-deltoid region or the thigh for young children
Administered 56 days after Ad26.ZEBOV with a window of -3,+10 days i.e. 53 to 66 days after Ad26.ZEBOV

Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	Zabdeno
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL at a dose of 5x10^10 viral particles in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization

Arm title	Placebo 0.5 mL (prime + boost; children)

Arm description: -

Arm type	Placebo
Investigational medicinal product name	NaCl 0.9%
Investigational medicinal product code	
Other name	Sodium chloride, saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL of 0.9% NaCl in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization and 56 days after with a window of -3,+10 days i.e. 53 to 66 days after first injection

Arm title	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)

Arm description: -

Arm type	Experimental
Investigational medicinal product name	NaCl 0.9%
Investigational medicinal product code	
Other name	Sodium chloride, saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL of 0.9% NaCl in the arm-deltoid region or the thigh for young children
Administered 56 days after rVSVΔG-ZEBOV-GP with a window of -3,+10 days i.e. 53 to 66 days after first injection

Investigational medicinal product name	rVSVΔG-ZEBOV-GP
Investigational medicinal product code	
Other name	Ervebo
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

For participants of the protocol v3.0: 1 mL at a dose at a labelled dose of ≥7.2 x 10^7 pfu/mL (with release specifications from 7.8x10^7 pfu/mL to 2.3x10^8 pfu/mL) in the arm-deltoid region or the thigh for young children after a 2-fold dilution in 0.9% saline
For participants of the protocol v4.0: 1 mL at a dose at a labelled dose of ≥7.2 x 10^7 pfu/mL (with release specifications from 7.8x10^7 pfu/mL to 2.3x10^8 pfu/mL) in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization

Arm title	rVSVΔG-ZEBOV-GP (prime + boost; children)

Arm description: -

Arm type	Experimental
Investigational medicinal product name	rVSVΔG-ZEBOV-GP
Investigational medicinal product code	
Other name	Ervebo
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

For participants of the protocol v3.0: 1 mL at a dose at a labelled dose of ≥7.2 x 10^7 pfu/mL (with release specifications from 7.8x10^7 pfu/mL to 2.3x10^8 pfu/mL) in the arm-deltoid region or the thigh for young children after a 2-fold dilution in 0.9% saline
For participants of the protocol v4.0: 1 mL at a dose at a labelled dose of ≥7.2 x 10^7 pfu/mL (with release specifications from 7.8x10^7 pfu/mL to 2.3x10^8 pfu/mL) in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization and 56 days after with a window of -3,+10 days i.e. 53 to 66 days after first injection

Arm title	Placebo 1 mL (prime + boost; children)

Arm description: -

Arm type	Placebo
Investigational medicinal product name	NaCl 0.9%
Investigational medicinal product code	
Other name	Sodium chloride, saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 mL of 0.9% NaCl in the arm-deltoid region or the thigh for young children
Administered the day of enrollment/randomization and 56 days after with a window of -3,+10 days i.e. 53 to 66 days after first injection

Number of subjects in period 1	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)	Placebo 0.5 mL (prime + boost; adults)	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)
Started	907	492	572
Completed	873	470	550
Not completed	34	22	22
Consent withdrawn by subject	1	2	3
Death	3	2	3
Missed visit	30	18	16

Number of subjects in period 1	rVSVΔG-ZEBOV-GP (prime + boost; adults)	Placebo 1 mL (prime + boost; adults)	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)
Started	296	291	664
Completed	283	277	644
Not completed	13	14	20
Consent withdrawn by subject	3	-	1
Death	-	-	-
Missed visit	10	14	19

Number of subjects in period 1	Placebo 0.5 mL (prime + boost; children)	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)	rVSVΔG-ZEBOV-GP (prime + boost; children)
Started	293	644	310
Completed	284	622	298
Not completed	9	22	12
Consent withdrawn by subject	1	4	1
Death	2	4	-
Missed visit	6	14	11

Number of subjects in period 1	Placebo 1 mL (prime + boost; children)
Started	317
Completed	307
Not completed	10
Consent withdrawn by subject	2
Death	1
Missed visit	7

Baseline characteristics

Reporting groups	
Reporting group title	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)
Reporting group description: -	
Reporting group title	Placebo 0.5 mL (prime + boost; adults)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP (prime + boost; adults)
Reporting group description: -	
Reporting group title	Placebo 1 mL (prime + boost; adults)
Reporting group description: -	
Reporting group title	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)
Reporting group description: -	
Reporting group title	Placebo 0.5 mL (prime + boost; children)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP (prime + boost; children)
Reporting group description: -	
Reporting group title	Placebo 1 mL (prime + boost; children)
Reporting group description: -	

Reporting group values	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)	Placebo 0.5 mL (prime + boost; adults)	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)
Number of subjects	907	492	572
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
median	27	28	28
inter-quartile range (Q1-Q3)	22 to 40	21 to 39	21 to 39
Gender categorical Units: Subjects			
Female	390	211	257
Male	517	281	315

Country of enrollment Units: Subjects			
Guinea	423	236	271
Liberia	282	150	106
Mali	81	48	84
Sierra Leone	121	58	111
HIV status			
Tested only in adults participants (18 years old and older)			
Units: Subjects			
HIV positive	17	11	17
HIV negative	890	481	555
Ebola Imunnoglobulin G concentration			
Tested only in protocol-v4.0 participants			
Units: Subjects			
< 66.96 EU/mL	142	78	144
≥ 66.96 and < 200 EU/mL	202	104	186
≥ 200 EU/mL	50	38	58
Unknown	513	272	184
Ebola Imunnoglobulin G concentration median			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL) median inter-quartile range (Q1-Q3)			
Ebola Immunoglobulin G concentration Geometric mean			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL) geometric mean standard deviation	±	±	±

Reporting group values	rVSVΔG-ZEBOV-GP (prime + boost; adults)	Placebo 1 mL (prime + boost; adults)	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)
Number of subjects	296	291	664
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
median	27	26	10
inter-quartile range (Q1-Q3)	21 to 37	21 to 38	5 to 14

Gender categorical Units: Subjects			
Female	130	130	327
Male	166	161	337
Country of enrollment Units: Subjects			
Guinea	143	139	340
Liberia	57	62	148
Mali	41	38	95
Sierra Leone	55	52	81
HIV status			
Tested only in adults participants (18 years old and older)			
Units: Subjects			
HIV positive	4	5	0
HIV negative	292	286	664
Ebola Imunnoglobulin G concentration			
Tested only in protocol-v4.0 participants			
Units: Subjects			
< 66.96 EU/mL	66	68	198
≥ 66.96 and < 200 EU/mL	99	91	157
≥ 200 EU/mL	32	30	43
Unknown	99	102	266
Ebola Imunnoglobulin G concentration median			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL) median inter-quartile range (Q1-Q3)			
Ebola Immunoglobulin G concentration Geometric mean			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL) geometric mean standard deviation	±	±	±

Reporting group values	Placebo 0.5 mL (prime + boost; children)	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)	rVSVΔG-ZEBOV-GP (prime + boost; children)
Number of subjects	293	644	310
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			

Age continuous			
Units: years			
median	10	10	10
inter-quartile range (Q1-Q3)	5 to 14	5 to 14	4 to 13
Gender categorical			
Units: Subjects			
Female	140	302	140
Male	153	342	170
Country of enrollment			
Units: Subjects			
Guinea	147	319	153
Liberia	63	140	65
Mali	40	94	46
Sierra Leone	43	91	46
HIV status			
Tested only in adults participants (18 years old and older)			
Units: Subjects			
HIV positive	0	0	0
HIV negative	293	644	310
Ebola Imunnoglobulin G concentration			
Tested only in protocol-v4.0 participants			
Units: Subjects			
< 66.96 EU/mL	87	187	97
≥ 66.96 and < 200 EU/mL	68	167	84
≥ 200 EU/mL	22	47	19
Unknown	116	243	110
Ebola Imunnoglobulin G concentration median			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
median			
inter-quartile range (Q1-Q3)			
Ebola Immunoglobulin G concentration Geometric mean			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
geometric mean			
standard deviation	±	±	±

Reporting group values	Placebo 1 mL (prime + boost; children)	Total	
Number of subjects	317	4786	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	

From 65-84 years		0	
85 years and over		0	

Age continuous			
Units: years			
median	9		
inter-quartile range (Q1-Q3)	4 to 13	-	
Gender categorical			
Units: Subjects			
Female	148	2175	
Male	169	2611	
Country of enrollment			
Units: Subjects			
Guinea	156	2327	
Liberia	60	1133	
Mali	51	618	
Sierra Leone	50	708	
HIV status			
Tested only in adults participants (18 years old and older)			
Units: Subjects			
HIV positive	0	54	
HIV negative	317	4732	
Ebola Imunnoglobulin G concentration			
Tested only in protocol-v4.0 participants			
Units: Subjects			
< 66.96 EU/mL	101	1168	
≥ 66.96 and < 200 EU/mL	76	1234	
≥ 200 EU/mL	32	371	
Unknown	108	2013	
Ebola Imunnoglobulin G concentration median			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
median			
inter-quartile range (Q1-Q3)		-	
Ebola Immunoglobulin G concentration Geometric mean			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
geometric mean			
standard deviation	±	-	

Subject analysis sets

Subject analysis set title	Pooled placebo groups (adults)
Subject analysis set type	Per protocol

Subject analysis set description:

The adult placebo groups (receiving either 0.5 or 1 mL placebo) are pooled for the analysis.

Subject analysis set title	Pooled placebo groups (children)
Subject analysis set type	Per protocol

Subject analysis set description:

The children placebo groups (receiving either 0.5 or 1 mL placebo) are pooled for the analysis.

Subject analysis set title	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Adults enrolled in the Ad26.ZEBOV prime + MVA-BN-Filo boost arm under protocol v4.0.	
Subject analysis set title	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Adults enrolled in the rVSVΔG-ZEBOV-GP prime with placebo booster arm under protocol v4.0.	
Subject analysis set title	rVSVΔG-ZEBOV-GP (prime + boost; adults; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Adults enrolled in the rVSVΔG-ZEBOV-GP prime + booster arm under protocol v4.0.	
Subject analysis set title	Pooled placebo groups (adults, v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Only the adults enrolled under v4.0 protocol are included in the analysis. Placebo groups (receiving either 0.5 or 1 mL placebo) are pooled for the analysis.	
Subject analysis set title	Ad26.ZEBOV prime + MVA-BN-Filo boost (children; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Children enrolled in the Ad26.ZEBOV prime + MVA-BN-Filo boost arm under protocol v4.0.	
Subject analysis set title	rVSVΔG-ZEBOV-GP prime + Placebo boost (children; v4.0 protoco)
Subject analysis set type	Per protocol
Subject analysis set description:	
Children enrolled in the rVSVΔG-ZEBOV-GP prime with placebo booster arm under protocol v4.0.	
Subject analysis set title	rVSVΔG-ZEBOV-GP (prime + boost; children; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Children enrolled in the rVSVΔG-ZEBOV-GP prime + booster arm under protocol v4.0.	
Subject analysis set title	Pooled placebo groups (children; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Only the children enrolled under v4.0 protocol are included in the analysis. Placebo groups (receiving either 0.5 or 1 mL placebo) are pooled for the analysis.	

Reporting group values	Pooled placebo groups (adults)	Pooled placebo groups (children)	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults; v4.0 protocol)
Number of subjects	783	610	396
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			

From 65-84 years			
85 years and over			

Age continuous			
Units: years			
median	28	10	27
inter-quartile range (Q1-Q3)	21 to 38	4 to 14	21 to 40
Gender categorical			
Units: Subjects			
Female	341	288	171
Male	442	322	225
Country of enrollment			
Units: Subjects			
Guinea	375	303	121
Liberia	212	123	73
Mali	86	91	81
Sierra Leone	110	93	121
HIV status			
Tested only in adults participants (18 years old and older)			
Units: Subjects			
HIV positive	16	0	6
HIV negative	767	610	390
Ebola Imunnoglobulin G concentration			
Tested only in protocol-v4.0 participants			
Units: Subjects			
< 66.96 EU/mL	146	188	142
≥ 66.96 and < 200 EU/mL	195	144	202
≥ 200 EU/mL	68	54	50
Unknown	374	224	2
Ebola Imunnoglobulin G concentration median			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
median			94
inter-quartile range (Q1-Q3)			43 to 149
Ebola Immunoglobulin G concentration Geometric mean			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
geometric mean			85
standard deviation	±	±	± 2.7

Reporting group values	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults; v4.0 protocol)	rVSVΔG-ZEBOV-GP (prime + boost; adults; v4.0 protocol)	Pooled placebo groups (adults, v4.0 protocol)
Number of subjects	395	197	412
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			

Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
median	27	26	
inter-quartile range (Q1-Q3)	20 to 39	20 to 35	
Gender categorical Units: Subjects			
Female	182	87	187
Male	213	110	225
Country of enrollment Units: Subjects			
Guinea	130	66	135
Liberia	70	35	81
Mali	84	41	86
Sierra Leone	111	55	110
HIV status			
Tested only in adults participants (18 years old and older)			
Units: Subjects			
HIV positive	13	2	4
HIV negative	382	195	408
Ebola Imunnoglobulin G concentration			
Tested only in protocol-v4.0 participants			
Units: Subjects			
< 66.96 EU/mL	144	66	146
≥ 66.96 and < 200 EU/mL	186	99	195
≥ 200 EU/mL	58	32	68
Unknown	7	0	3
Ebola Imunnoglobulin G concentration median			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
median	92	94	96
inter-quartile range (Q1-Q3)	45 to 145	46 to 143	47 to 156
Ebola Immunoglobulin G concentration Geometric mean			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
geometric mean	87	91	
standard deviation	± 2.7	± 2.7	±

Reporting group values	Ad26.ZEBOV prime + MVA-BN-Filo boost (children; v4.0 protocol)	rVSVΔG-ZEBOV-GP prime + Placebo boost (children; v4.0 protoco)	rVSVΔG-ZEBOV-GP (prime + boost; children; v4.0 protocol)
Number of subjects	403	407	202

Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
median	8	9	8
inter-quartile range (Q1-Q3)	4 to 13	4 to 12	3 to 13
Gender categorical Units: Subjects			
Female	186	185	85
Male	217	222	117
Country of enrollment Units: Subjects			
Guinea	163	156	77
Liberia	64	66	33
Mali	95	94	46
Sierra Leone	81	91	46
HIV status			
Tested only in adults participants (18 years old and older)			
Units: Subjects			
HIV positive	0	0	0
HIV negative	403	407	202
Ebola Imunnoglobulin G concentration			
Tested only in protocol-v4.0 participants			
Units: Subjects			
< 66.96 EU/mL	198	187	97
≥ 66.96 and < 200 EU/mL	157	167	84
≥ 200 EU/mL	43	47	19
Unknown	5	6	2
Ebola Imunnoglobulin G concentration median			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
median	67	74	69
inter-quartile range (Q1-Q3)	29 to 127	33 to 122	33 to 122
Ebola Immunoglobulin G concentration Geometric mean			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL)			
geometric mean	63	67	67
standard deviation	± 3.0	± 3.0	± 3.1

Reporting group values	Pooled placebo		

	groups (children; v4.0 protocol)		
Number of subjects	389		
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years median inter-quartile range (Q1-Q3)			
Gender categorical Units: Subjects			
Female	182		
Male	207		
Country of enrollment Units: Subjects			
Guinea	150		
Liberia	55		
Mali	91		
Sierra Leone	93		
HIV status			
Tested only in adults participants (18 years old and older)			
Units: Subjects			
HIV positive	0		
HIV negative	389		
Ebola Imunnoglobulin G concentration			
Tested only in protocol-v4.0 participants			
Units: Subjects			
< 66.96 EU/mL	188		
≥ 66.96 and < 200 EU/mL	144		
≥ 200 EU/mL	54		
Unknown	3		
Ebola Imunnoglobulin G concentration median			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL) median inter-quartile range (Q1-Q3)	 71 33 to 141		
Ebola Immunoglobulin G concentration Geometric mean			
Tested only in protocol-v4.0 participants			
Units: ELISA Unit per milliliters (EU/mL) geometric mean			

standard deviation	±		

End points

End points reporting groups

Reporting group title	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)
Reporting group description: -	
Reporting group title	Placebo 0.5 mL (prime + boost; adults)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP (prime + boost; adults)
Reporting group description: -	
Reporting group title	Placebo 1 mL (prime + boost; adults)
Reporting group description: -	
Reporting group title	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)
Reporting group description: -	
Reporting group title	Placebo 0.5 mL (prime + boost; children)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP (prime + boost; children)
Reporting group description: -	
Reporting group title	Placebo 1 mL (prime + boost; children)
Reporting group description: -	
Subject analysis set title	Pooled placebo groups (adults)
Subject analysis set type	Per protocol
Subject analysis set description:	
The adult placebo groups (receiving either 0.5 or 1 mL placebo) are pooled for the analysis.	
Subject analysis set title	Pooled placebo groups (children)
Subject analysis set type	Per protocol
Subject analysis set description:	
The children placebo groups (receiving either 0.5 or 1 mL placebo) are pooled for the analysis.	
Subject analysis set title	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Adults enrolled in the Ad26.ZEBOV prime + MVA-BN-Filo boost arm under protocol v4.0.	
Subject analysis set title	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Adults enrolled in the rVSVΔG-ZEBOV-GP prime with placebo booster arm under protocol v4.0.	
Subject analysis set title	rVSVΔG-ZEBOV-GP (prime + boost; adults; v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Adults enrolled in the rVSVΔG-ZEBOV-GP prime + booster arm under protocol v4.0.	
Subject analysis set title	Pooled placebo groups (adults, v4.0 protocol)
Subject analysis set type	Per protocol
Subject analysis set description:	
Only the adults enrolled under v4.0 protocol are included in the analysis. Placebo groups (receiving either 0.5 or 1 mL placebo) are pooled for the analysis.	
Subject analysis set title	Ad26.ZEBOV prime + MVA-BN-Filo boost (children; v4.0 protocol)

Subject analysis set type	Per protocol

Subject analysis set description:

Children enrolled in the Ad26.ZEBOV prime + MVA-BN-Filo boost arm under protocol v4.0.

Subject analysis set title	rVSVΔG-ZEBOV-GP prime + Placebo boost (children; v4.0 protoco)
Subject analysis set type	Per protocol

Subject analysis set description:

Children enrolled in the rVSVΔG-ZEBOV-GP prime with placebo booster arm under protocol v4.0.

Subject analysis set title	rVSVΔG-ZEBOV-GP (prime + boost; children; v4.0 protocol)
Subject analysis set type	Per protocol

Subject analysis set description:

Children enrolled in the rVSVΔG-ZEBOV-GP prime + booster arm under protocol v4.0.

Subject analysis set title	Pooled placebo groups (children; v4.0 protocol)
Subject analysis set type	Per protocol

Subject analysis set description:

Only the children enrolled under v4.0 protocol are included in the analysis. Placebo groups (receiving either 0.5 or 1 mL placebo) are pooled for the analysis.

Primary: Percentage of Participants With Ebola Virus Glycoprotein (GP-EBOV) Antibody Response

End point title	Percentage of Participants With Ebola Virus Glycoprotein (GP-EBOV) Antibody Response[1]

End point description:

Antibody responder at 12 months is defined as a participant who experiences a 4-fold increase in antibody level from baseline and for whom the antibody level at 12 months is greater than or equal to 200 EU/mL.
The analysis population only includes participants from version 4.0 of the protocol (milestone protocol v4.0). Participants with a missing baseline or 12-month antibody result are excluded. Participants with elevated antibody levels at baseline were not excluded. The placebo group is pooled.

End point type	Primary

End point timeframe:

Measured through Month 12

Notes:

[1] - 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: The analysis population only includes participants from version 4.0 of the protocol (milestone protocol v4.0).

End point values	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)	rVSVΔG-ZEBOV-GP (prime + boost; adults)	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	374	371	185	381
Units: Participants	153	281	150	299

End point values	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)	rVSVΔG-ZEBOV-GP (prime + boost; children)	Pooled placebo groups (adults)	Pooled placebo groups (children)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	385	189	377	364
Units: Participants	336	175	10	13

Statistical analyses

Statistical analysis title	Interim analysis
Comparison groups	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults) v rVSVΔG-ZEBOV-GP prime + Placebo boost (adults) v rVSVΔG-ZEBOV-GP (prime + boost; adults) v Ad26.ZEBOV prime + MVA-BN-Filo boost (children) v rVSVΔG-ZEBOV-GP (prime + boost; children) v rVSVΔG-ZEBOV-GP prime + Placebo boost (children) v Pooled placebo groups (adults) v Pooled placebo groups (children)
Number of subjects included in analysis	2626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Cochran-Mantel-Haenszel

Notes:

[2] - Each active group is compared to placebo using a 2-sided .0167 significance level.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

12 months for the Primary Outcome.

Adverse event reporting additional description:

AEs of grade 1 or 2 severity other than injection site reactions and targeted symptoms were not collected.
Systematically assessed AEs were collected via standard checklist.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)
Reporting group description: -	
Reporting group title	Placebo 0.5 mL (prime + boost; adults)
Reporting group description: -	
Reporting group title	Placebo 1 mL (prime + boost; children)
Reporting group description: -	
Reporting group title	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)
Reporting group description: -	
Reporting group title	Placebo 0.5 mL (prime + boost; children)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP (prime + boost; children)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP (prime + boost; adults)
Reporting group description: -	
Reporting group title	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)
Reporting group description: -	
Reporting group title	Placebo 1 mL (prime + boost; adults)

Reporting group description: -

Serious adverse events	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)	Placebo 0.5 mL (prime + boost; adults)	Placebo 1 mL (prime + boost; children)
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 907 (3.53%)	12 / 492 (2.44%)	9 / 317 (2.84%)
number of deaths (all causes)	3	2	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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 incomplete			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Abortion spontaneous			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Abortion incomplete			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Ectopic pregnancy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Premature separation of placenta			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Obstructed labour			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine contractions during pregnancy			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Drowning			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Immune system disorders			
Anaphylactic reaction			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Metrorrhagia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Vaginal discharge			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Genital haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	1 / 492 (0.20%)	0 / 317 (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
Asthmatic crisis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Injury, poisoning and procedural complications			
Ankle fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Burns second degree			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Humerus fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Lower limb fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Burns first degree			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Road traffic accident			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	1 / 492 (0.20%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 907 (0.22%)	0 / 492 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Snake bite			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venom poisoning			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Wrist fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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 injury alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Jaw fracture alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Limb injury			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Wound secretion alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Ulna fracture alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Fracture alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Tibia fracture alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Fibula fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Nervous system disorders			
Cerebrovascular accident			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	1 / 492 (0.20%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ischaemic stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	1 / 492 (0.20%)	0 / 317 (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
Sickle cell anaemia with crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Anaemia of pregnancy			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness unilateral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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			
Abdominal pain lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Abdominal hernia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	1 / 492 (0.20%)	0 / 317 (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
Abdominal pain upper			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Acute abdomen			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 907 (0.00%)	1 / 492 (0.20%)	0 / 317 (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
Inguinal hernia			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 907 (0.44%)	1 / 492 (0.20%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Peritoneal haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Inguinal hernia, obstructive			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Gastric perforation			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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

Subileus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Skin and subcutaneous tissue disorders			
Skin ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	1 / 492 (0.20%)	0 / 317 (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
Pruritus generalised			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Compartment syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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			
Abscess limb			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Appendicitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 907 (0.88%)	2 / 492 (0.41%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	1 / 492 (0.20%)	0 / 317 (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
Gastroenteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	1 / 492 (0.20%)	2 / 317 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIV infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Peritonitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Pulmonary tuberculosis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Wound infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	1 / 317 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Genital infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	1 / 492 (0.20%)	0 / 317 (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
Salmonellosis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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

Salpingitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 907 (0.11%)	0 / 492 (0.00%)	0 / 317 (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
Furuncle			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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			
Diabetes mellitus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	1 / 492 (0.20%)	0 / 317 (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
Diabetes mellitus inadequate control			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Ketoacidosis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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
Malnutrition			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 907 (0.00%)	0 / 492 (0.00%)	0 / 317 (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	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)	Placebo 0.5 mL (prime + boost; children)	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 664 (1.51%)	6 / 293 (2.05%)	15 / 644 (2.33%)
number of deaths (all causes)	0	2	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Vascular disorders			
Hypertension			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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 incomplete			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Abortion spontaneous			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Abortion incomplete			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Premature separation of placenta			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Obstructed labour			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Uterine contractions during pregnancy			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	2 / 644 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Drowning			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 664 (0.00%)	1 / 293 (0.34%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Reproductive system and breast disorders			
Metrorrhagia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Pelvic pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Vaginal discharge			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital haemorrhage			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Asthmatic crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Head injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Humerus fracture			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Lower limb fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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 first degree			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (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
Road traffic accident			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Radius fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Clavicle fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Snake bite			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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

Venom poisoning alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	1 / 293 (0.34%)	0 / 644 (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
Wrist fracture alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye injury alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Jaw fracture alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Limb injury subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Wound secretion alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Ulna fracture alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (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
Tibia fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (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
Fibula fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Ischaemic stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Sickle cell anaemia with crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	1 / 293 (0.34%)	0 / 644 (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
Anaemia of pregnancy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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			
Blindness unilateral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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			
Abdominal pain lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Abdominal hernia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Abdominal pain upper			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Acute abdomen			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	2 / 644 (0.31%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Inguinal hernia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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 obstruction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Peritoneal haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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

Gastric perforation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Subileus			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (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
Skin and subcutaneous tissue disorders			
Skin ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Pruritus generalised			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Musculoskeletal and connective tissue disorders			
Compartment syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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			

Abscess limb alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Appendicitis alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 664 (0.45%)	3 / 293 (1.02%)	3 / 644 (0.47%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Gastroenteritis alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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 alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
HIV infection alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Peritonitis alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Sepsis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	1 / 644 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (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
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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

Genital infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Salmonellosis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Salpingitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Pyelonephritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Furuncle			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (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
Metabolism and nutrition disorders			
Diabetes mellitus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Diabetes mellitus inadequate control			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Ketoacidosis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 664 (0.00%)	0 / 293 (0.00%)	0 / 644 (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
Malnutrition			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 664 (0.15%)	0 / 293 (0.00%)	0 / 644 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	rVSVΔG-ZEBOV-GP (prime + boost; children)	rVSVΔG-ZEBOV-GP (prime + boost; adults)	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 310 (1.29%)	3 / 296 (1.01%)	12 / 572 (2.10%)
number of deaths (all causes)	0	0	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	1 / 296 (0.34%)	0 / 572 (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
Vascular disorders			
Hypertension			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous incomplete			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Abortion spontaneous			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Abortion incomplete			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Ectopic pregnancy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Obstructed labour			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Uterine contractions during pregnancy			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
General disorders and administration site conditions			
Death			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Drowning			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Immune system disorders			
Anaphylactic reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Reproductive system and breast disorders			
Metrorrhagia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Vaginal discharge			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Genital haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Asthmatic crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Injury, poisoning and procedural complications			
Ankle fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Head injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	1 / 296 (0.34%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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 first degree			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Road traffic accident			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Radius fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 310 (0.32%)	0 / 296 (0.00%)	0 / 572 (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

Clavicle fracture alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Snake bite alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Venom poisoning alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Wrist fracture alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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 injury alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 310 (0.32%)	0 / 296 (0.00%)	0 / 572 (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
Jaw fracture alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			

subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Wound secretion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Ulna fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Tibia fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Fibula fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Nervous system disorders			
Cerebrovascular accident			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Ischaemic stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 310 (0.32%)	0 / 296 (0.00%)	0 / 572 (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
Sickle cell anaemia with crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Anaemia of pregnancy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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			
Blindness unilateral			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 310 (0.32%)	0 / 296 (0.00%)	0 / 572 (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			
Abdominal pain lower			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Abdominal hernia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Abdominal pain upper			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	1 / 296 (0.34%)	0 / 572 (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
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Inguinal hernia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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 obstruction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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

Peritoneal haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Inguinal hernia, obstructive			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Gastric perforation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Subileus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Skin and subcutaneous tissue disorders			
Skin ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Pruritus generalised			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Musculoskeletal and connective tissue disorders			
Compartment syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	1 / 296 (0.34%)	0 / 572 (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
Infections and infestations			
Abscess limb			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Appendicitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 310 (0.32%)	0 / 296 (0.00%)	3 / 572 (0.52%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cellulitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Gastroenteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 310 (0.32%)	0 / 296 (0.00%)	0 / 572 (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
HIV infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Peritonitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary tuberculosis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Wound infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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

Pneumonia alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Urinary tract infection alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital infection alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Salmonellosis alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Salpingitis alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Pyelonephritis alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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
Furuncle alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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			
Diabetes mellitus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ketoacidosis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	1 / 572 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 310 (0.00%)	0 / 296 (0.00%)	0 / 572 (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	Placebo 1 mL (prime + boost; adults)		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 291 (1.37%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Hypertension				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous incomplete				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 291 (0.34%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abortion spontaneous				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abortion incomplete				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ectopic pregnancy				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Premature separation of placenta				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructed labour				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine contractions during pregnancy				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Death				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drowning				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Anaphylactic reaction				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Metrorrhagia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal discharge			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Genital haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthmatic crisis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burns second degree			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 291 (0.34%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burns first degree			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clavicle fracture				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Snake bite				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venom poisoning				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Eye injury				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaw fracture				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb injury				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound secretion				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulna fracture				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fracture				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibula fracture				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebrovascular accident				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sickle cell anaemia with crisis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia of pregnancy				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Blindness unilateral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute abdomen			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal obstruction				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritoneal haemorrhage				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia, obstructive				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric perforation				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Subileus				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Skin ulcer				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pruritus generalised				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Compartment syndrome				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess limb				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 291 (0.34%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 291 (0.34%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malaria				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HIV infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Typhoid fever				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Genital infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Salmonellosis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Salpingitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Furuncle				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Diabetes mellitus				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus inadequate control				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ketoacidosis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 291 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malnutrition				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 291 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Ad26.ZEBOV prime + MVA-BN-Filo boost (adults)	Placebo 0.5 mL (prime + boost; adults)	Placebo 1 mL (prime + boost; children)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	670 / 907 (73.87%)	326 / 492 (66.26%)	237 / 317 (74.76%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	108 / 907 (11.91%)	62 / 492 (12.60%)	24 / 317 (7.57%)
occurrences (all)	133	81	42
Headache			
subjects affected / exposed	488 / 907 (53.80%)	247 / 492 (50.20%)	128 / 317 (40.38%)
occurrences (all)	852	428	300
General disorders and administration site conditions			
Chills			
subjects affected / exposed	112 / 907 (12.35%)	43 / 492 (8.74%)	47 / 317 (14.83%)
occurrences (all)	124	48	72
Fatigue			
subjects affected / exposed	226 / 907 (24.92%)	115 / 492 (23.37%)	52 / 317 (16.40%)
occurrences (all)	341	161	90
Pyrexia			
subjects affected / exposed	277 / 907 (30.54%)	114 / 492 (23.17%)	146 / 317 (46.06%)
occurrences (all)	362	155	274
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	154 / 907 (16.98%)	82 / 492 (16.67%)	61 / 317 (19.24%)
occurrences (all)	205	106	133
Diarrhoea			
subjects affected / exposed	32 / 907 (3.53%)	17 / 492 (3.46%)	35 / 317 (11.04%)
occurrences (all)	35	21	45
Nausea			

subjects affected / exposed	65 / 907 (7.17%)	42 / 492 (8.54%)	21 / 317 (6.62%)
occurrences (all)	77	57	32
Vomiting			
subjects affected / exposed	18 / 907 (1.98%)	17 / 492 (3.46%)	27 / 317 (8.52%)
occurrences (all)	19	18	40
Skin and subcutaneous tissue disorders			
Skin lesion			
subjects affected / exposed	58 / 907 (6.39%)	27 / 492 (5.49%)	30 / 317 (9.46%)
occurrences (all)	67	34	45
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	197 / 907 (21.72%)	78 / 492 (15.85%)	19 / 317 (5.99%)
occurrences (all)	286	103	28
Myalgia			
subjects affected / exposed	237 / 907 (26.13%)	101 / 492 (20.53%)	38 / 317 (11.99%)
occurrences (all)	307	123	43
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	139 / 907 (15.33%)	63 / 492 (12.80%)	68 / 317 (21.45%)
occurrences (all)	185	87	110

Non-serious adverse events	Ad26.ZEBOV prime + MVA-BN-Filo boost (children)	Placebo 0.5 mL (prime + boost; children)	rVSVΔG-ZEBOV-GP prime + Placebo boost (children)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	531 / 664 (79.97%)	208 / 293 (70.99%)	536 / 644 (83.23%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	49 / 664 (7.38%)	22 / 293 (7.51%)	76 / 644 (11.80%)
occurrences (all)	88	32	125
Headache			
subjects affected / exposed	289 / 664 (43.52%)	117 / 293 (39.93%)	341 / 644 (52.95%)
occurrences (all)	688	253	819
General disorders and administration site conditions			
Chills			
subjects affected / exposed	112 / 664 (16.87%)	35 / 293 (11.95%)	116 / 644 (18.01%)
occurrences (all)	167	48	180
Fatigue			

subjects affected / exposed	142 / 664 (21.39%)	41 / 293 (13.99%)	171 / 644 (26.55%)
occurrences (all)	236	59	286
Pyrexia			
subjects affected / exposed	357 / 664 (53.77%)	115 / 293 (39.25%)	392 / 644 (60.87%)
occurrences (all)	706	227	827
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	152 / 664 (22.89%)	57 / 293 (19.45%)	153 / 644 (23.76%)
occurrences (all)	268	84	286
Diarrhoea			
subjects affected / exposed	32 / 664 (4.82%)	23 / 293 (7.85%)	47 / 644 (7.30%)
occurrences (all)	55	36	61
Nausea			
subjects affected / exposed	48 / 664 (7.23%)	17 / 293 (5.80%)	52 / 644 (8.07%)
occurrences (all)	71	23	77
Vomiting			
subjects affected / exposed	72 / 664 (10.84%)	27 / 293 (9.22%)	74 / 644 (11.49%)
occurrences (all)	97	34	106
Skin and subcutaneous tissue disorders			
Skin lesion			
subjects affected / exposed	65 / 664 (9.79%)	29 / 293 (9.90%)	60 / 644 (9.32%)
occurrences (all)	101	44	91
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	56 / 664 (8.43%)	14 / 293 (4.78%)	69 / 644 (10.71%)
occurrences (all)	83	20	112
Myalgia			
subjects affected / exposed	102 / 664 (15.36%)	25 / 293 (8.53%)	128 / 644 (19.88%)
occurrences (all)	146	32	180
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	152 / 664 (22.89%)	43 / 293 (14.68%)	178 / 644 (27.64%)
occurrences (all)	256	65	330

Non-serious adverse events	rVSVΔG-ZEBOV-GP (prime + boost; children)	rVSVΔG-ZEBOV-GP (prime + boost; adults)	rVSVΔG-ZEBOV-GP prime + Placebo boost (adults)
Total subjects affected by non-serious adverse events			

subjects affected / exposed	263 / 310 (84.84%)	235 / 296 (79.39%)	468 / 572 (81.82%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	28 / 310 (9.03%)	31 / 296 (10.47%)	93 / 572 (16.26%)
occurrences (all)	49	40	112
Headache			
subjects affected / exposed	153 / 310 (49.35%)	182 / 296 (61.49%)	364 / 572 (63.64%)
occurrences (all)	383	319	661
General disorders and administration site conditions			
Chills			
subjects affected / exposed	46 / 310 (14.84%)	51 / 296 (17.23%)	112 / 572 (19.58%)
occurrences (all)	65	59	137
Fatigue			
subjects affected / exposed	75 / 310 (24.19%)	98 / 296 (33.11%)	187 / 572 (32.69%)
occurrences (all)	128	143	257
Pyrexia			
subjects affected / exposed	190 / 310 (61.29%)	121 / 296 (40.88%)	249 / 572 (43.53%)
occurrences (all)	398	173	338
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	68 / 310 (21.94%)	56 / 296 (18.92%)	118 / 572 (20.63%)
occurrences (all)	130	79	154
Diarrhoea			
subjects affected / exposed	26 / 310 (8.39%)	10 / 296 (3.38%)	27 / 572 (4.72%)
occurrences (all)	35	15	29
Nausea			
subjects affected / exposed	21 / 310 (6.77%)	33 / 296 (11.15%)	70 / 572 (12.24%)
occurrences (all)	30	43	87
Vomiting			
subjects affected / exposed	36 / 310 (11.61%)	14 / 296 (4.73%)	31 / 572 (5.42%)
occurrences (all)	52	15	34
Skin and subcutaneous tissue disorders			
Skin lesion			
subjects affected / exposed	27 / 310 (8.71%)	15 / 296 (5.07%)	39 / 572 (6.82%)
occurrences (all)	44	16	48
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	26 / 310 (8.39%)	74 / 296 (25.00%)	151 / 572 (26.40%)
occurrences (all)	42	106	212
Myalgia			
subjects affected / exposed	57 / 310 (18.39%)	101 / 296 (34.12%)	199 / 572 (34.79%)
occurrences (all)	87	132	267
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	85 / 310 (27.42%)	56 / 296 (18.92%)	130 / 572 (22.73%)
occurrences (all)	159	70	171

Non-serious adverse events	Placebo 1 mL (prime + boost; adults)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	213 / 291 (73.20%)		
Nervous system disorders			
Dizziness			
subjects affected / exposed	36 / 291 (12.37%)		
occurrences (all)	42		
Headache			
subjects affected / exposed	156 / 291 (53.61%)		
occurrences (all)	294		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	42 / 291 (14.43%)		
occurrences (all)	51		
Fatigue			
subjects affected / exposed	77 / 291 (26.46%)		
occurrences (all)	102		
Pyrexia			
subjects affected / exposed	97 / 291 (33.33%)		
occurrences (all)	142		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	54 / 291 (18.56%)		
occurrences (all)	72		
Diarrhoea			

subjects affected / exposed	16 / 291 (5.50%)		
occurrences (all)	17		
Nausea			
subjects affected / exposed	29 / 291 (9.97%)		
occurrences (all)	33		
Vomiting			
subjects affected / exposed	13 / 291 (4.47%)		
occurrences (all)	14		
Skin and subcutaneous tissue disorders			
Skin lesion			
subjects affected / exposed	14 / 291 (4.81%)		
occurrences (all)	22		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	55 / 291 (18.90%)		
occurrences (all)	80		
Myalgia			
subjects affected / exposed	68 / 291 (23.37%)		
occurrences (all)	88		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	51 / 291 (17.53%)		
occurrences (all)	56		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 August 2017	Version 3.0 of the PREVAC Protocol Under Version 3.0 of the PREVAC protocol 1,450 participants were randomized to one of five groups: 1) Ad26.ZEBOV (prime) followed by an MVA-BN-Filo boost at 56 days; 2) rVSVΔG-ZEBOV-GP (prime, diluted dose) with a placebo boost at 56 days; 3) rVSVΔG-ZEBOV-GP (prime, diluted dose) with a rVSVΔG-ZEBOV-GP boost (diluted) at 56 days; 4) placebo for rVSVΔG-ZEBOV-GP; or 5) placebo for the Ad26.ZEBOV and MVA-BN-Filo vaccines. The rVSVΔG-ZEBOV-GP vaccine was given at a 2-fold dilution in Version 3.0 because the certificate of analysis of the vaccine lot was found to be higher than that used in the PREVAIL I trial in Liberia. Variation in titer/potency in live virus vaccines is common. Vaccine manufacture and release for potency is based upon defined specifications and always encompasses a range, routinely with a lower and upper limit. The lower limit, referred to as the nominal dose, is determined during development and is defined by the lowest dose for which there is demonstrated efficacy. The lower limit for potency must still be valid at the end of shelf-life in order to ensure that the vaccine is still efficacious up until its defined expiry. Since there were limited numbers of children in previous studies of the rVSVΔG-ZEBOV-GP vaccine, Version 3.0 of PREVAC used a measured approach with dilution of the rVSVΔG-ZEBOV-GP vaccine. The Version 3.0 amendment also updated the safety information for the rVSVΔG-ZEBOV-GP vaccine, removed language about the initial phase of PREVAC described in Version 2.0, and included minor edits to the Saliva Sample Substudy in Appendix E. The data collection plan for Version 3.0 was the same as that described in Version 1.0 and Version 2.0.

15 March 2018	Version 4.0 of the PREVAC Protocol Version 4.0 of the protocol did not begin until at least 70 children in each of the three age groups (1-4, 5-11, and 12-17 years) were enrolled in Version 3.0 and the DSMB reviewed safety data through 28 days for each age group. Under Version 4.0 of the PREVAC protocol, a target of 2,800 participants (1,400 adults and 1,400 children) to be randomized to one of five groups was reached: 1) Ad26.ZEBOV (prime) followed by an MVA-BN-Filo boost at 56 days; 2) rVSVΔG-ZEBOV-GP (prime, undiluted dose) with a placebo boost at 56 days; 3) rVSVΔG-ZEBOV-GP (prime, undiluted dose) with a rVSVΔG-ZEBOV-GP boost (undiluted) at 56 days; 4) placebo for rVSVΔG-ZEBOV-GP; or 5) placebo for the Ad26.ZEBOV and MVA-BN-Filo vaccines. In addition to the dosing information for the rVSVΔG-ZEBOV-GP vaccine, the version 4.0 amendment also updated the safety information for the rVSVΔG-ZEBOV-GP vaccine, and amended the Immunological Substudy in Appendix D and the Saliva Substudy in Appendix E. The Immunological Substudy was amended to state that up to 230 participants were to be enrolled in Versions 2.0, 3.0, and 4.0 (in total). The Saliva Substudy was amended to state that the target sample size was 140 children, with approximately an equal distribution of children in each of the three age groups (1-4, 5-11, and 12-17 years), for both Version 3.0 and Version 4.0 of PREVAC. While the primary objectives of PREVAC will be accomplished with participants enrolled under Version 4.0, the participants randomized under Versions 2.0 and 3.0 will contribute to the evaluation of each of the objectives that compares the rHAd26/MVA vaccine strategy to placebo. In addition, participants enrolled under Version 3.0 of the protocol will provide information on the safety and immunogenicity of the diluted dose of the rVSVΔG-ZEBOV-GP vaccine compared to placebo for adults and children in each of the three age groups (1-4, 5-11, and 12-17 years).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33485369

http://www.ncbi.nlm.nih.gov/pubmed/36516078