Clinical trial results:
A phase III, open, controlled study in South Africa to assess the immunogenicity, safety and reactogenicity of GSK Biologicals' 10-valent pneumococcal conjugate vaccine administered as a 3-dose (6, 10, 14 weeks) primary immunization course in HIV infected infants, HIV exposed uninfected infants and HIV unexposed uninfected infants followed by a booster vaccination at 9-10 months of age.

Summary

EudraCT number	2011-002077-35
Trial protocol	Outside EU/EEA
Global end of trial date	27 June 2012

Results information

Result version number	v3 (current)
This version publication date	26 February 2023
First version publication date	11 June 2015
Version creation reason	• Correction of full data set Correction of full data set and alignment between registries.

Trial information

Trial identification

Sponsor protocol code	111634

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00829010
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000673-PIP01-09
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 April 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 June 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate and characterize the immune response to the Synflorix vaccine one month following a 3-dose (6, 10 and 14 weeks of age) primary vaccination course in HIV infected infants, HIV exposed uninfected infants and HIV unexposed uninfected infants.

Protection of trial subjects:

All subjects were supervised after vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Only eligible subjects that had no contraindications to any components of the vaccines were vaccinated. Subjects were followed-up after each vaccination.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	17 February 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	South Africa: 489
Worldwide total number of subjects	489
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)	489
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The oral poliovirus vaccine could be given at any time during the study (routinely given concurrently with Tritanrix-HepB/Hib vaccine) but was not considered as study vaccine. Out of the 489 subjects enrolled in the study, only 484 subjects were assigned to a study group and received vaccination.

Pre-assignment

Screening details:

The study included 3 populations defined based on the human immunodeficiency virus status of the mother and the infant. Infant born from: •a HIV positive mother and HIV infected at Month 0 = HIV+/+. •a HIV positive mother and HIV exposed uninfected at screening = HIV+/-. •a HIV negative mother and HIV unexposed uninfected at Month 0 = HIV-.

Pre-assignment period milestones

Number of subjects started	489
Number of subjects completed	484

Pre-assignment subject non-completion reasons

Reason: Number of subjects	No study vacccination received: 5

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	HIV+/+ Group

Arm description:

Infants born from a HIV positive mother and confirmed as HIV infected. Subjects received 3 primary doses (at 6, 10 and 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 and 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 and 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age and 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered intramuscularly in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix given orally.

Arm type	Experimental
Investigational medicinal product name	Synflorix
Investigational medicinal product code	GSK1024850A
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8).

Investigational medicinal product name	Tritanrix-HepB/Hib
Investigational medicinal product code	
Other name	DTPW-HBV/Hib, Diphteria toxoid
Pharmaceutical forms	Suspension for injection

Routes of administration	Intramuscular use

Dosage and administration details:

Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14).

Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	HRV
Pharmaceutical forms	Powder and solvent for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received 2 vaccine doses (at 10 & 14 weeks of age, at study Months 1 and 2).

Investigational medicinal product name	Measles
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 2 doses at 9-10 months and 15-18 months of age.

Arm title	HIV+/- Group

Arm description:

Infants born from a HIV positive mother and confirmed as HIV exposed uninfected.Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Arm type	Experimental
Investigational medicinal product name	Synflorix
Investigational medicinal product code	GSK1024850A
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8).

Investigational medicinal product name	Tritanrix-HepB/Hib
Investigational medicinal product code	
Other name	DTPW-HBV/Hib
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14).

Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	HRV
Pharmaceutical forms	Powder and solvent for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received 2 vaccine doses (at 10 & 14 weeks of age, at study Months 1 and 2).

Investigational medicinal product name	Measles
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 2 doses at 9-10 months and 15-18 months of age.

Arm title	HIV-(3+1) Group

Arm description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Arm type	Experimental
Investigational medicinal product name	Synflorix
Investigational medicinal product code	GSK1024850A
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8).

Investigational medicinal product name	Tritanrix-HepB/Hib
Investigational medicinal product code	
Other name	DTPW-HBV/Hib
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14).

Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	HRV
Pharmaceutical forms	Powder and solvent for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received 2 vaccine doses (at 10 & 14 weeks of age, at study Months 1 and 2).

Investigational medicinal product name	Measles
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 2 doses at 9-10 months and 15-18 months of age.

Arm title	HIV- (3+0) Group

Arm description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 3 primary doses of Synflorix vaccine (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1

and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix™-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Arm type	Experimental
Investigational medicinal product name	Synflorix
Investigational medicinal product code	GSK1024850A
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2).

Investigational medicinal product name	Tritanrix-HepB/Hib
Investigational medicinal product code	
Other name	DTPW-HBV/Hib; Diphteria toxoid
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14).

Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	HRV
Pharmaceutical forms	Powder and solvent for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received 2 vaccine doses (at 10 & 14 weeks of age, at study Months 1 and 2).

Investigational medicinal product name	Measles
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 2 doses at 9-10 months and 15-18 months of age.

Arm title	HIV-(2+1) Group

Arm description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 2 primary doses (at 6 & 14 weeks of age at study Months 0 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Arm type	Experimental
Investigational medicinal product name	Synflorix
Investigational medicinal product code	GSK1024850A
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:	
Subjects received 2 primary doses (at 6 & 14 weeks of age, at study Months 0 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8).	
Investigational medicinal product name	Tritanrix-HepB/Hib
Investigational medicinal product code	
Other name	DTPW-HBV/Hib
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14).	
Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	HRV
Pharmaceutical forms	Powder and solvent for oral suspension
Routes of administration	Oral use
Dosage and administration details:	
Subjects received 2 vaccine doses (at 10 & 14 weeks of age, at study Months 1 and 2).	
Investigational medicinal product name	Measles
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received 2 doses at 9-10 months and 15-18 months of age.	

Number of subjects in period 1[1]	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group
Started	83	101	100
Completed	73	92	97
Not completed	10	9	3
Consent withdrawn by subject	-	1	1
Adverse event, non-fatal	1	-	-
Death	5	4	-
Migrated/moved from study area	3	4	-
Lost to follow-up	1	-	2

Number of subjects in period 1[1]	HIV- (3+0) Group	HIV-(2+1) Group
Started	100	100
Completed	92	98
Not completed	8	2
Consent withdrawn by subject	-	2
Adverse event, non-fatal	-	-
Death	3	-
Migrated/moved from study area	5	-

Lost to follow-up	-	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 5 enrolled subjects were not allocated to a group and did not receive a vaccine.

Baseline characteristics

Reporting groups

Reporting group title	HIV+/+ Group

Reporting group description:

Infants born from a HIV positive mother and confirmed as HIV infected. Subjects received 3 primary doses (at 6, 10 and 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 and 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 and 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age and 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered intramuscularly in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix given orally.

Reporting group title	HIV+/- Group

Reporting group description:

Infants born from a HIV positive mother and confirmed as HIV exposed uninfected.Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV-(3+1) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV- (3+0) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 3 primary doses of Synflorix vaccine (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix™-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV-(2+1) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 2 primary doses (at 6 & 14 weeks of age at study Months 0 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group
Number of subjects	83	101	100
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	83	101	100
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: weeks			
arithmetic mean	6.6	6.3	6.1
standard deviation	± 0.92	± 0.65	± 0.41
Gender categorical Units: Subjects			
Female	49	47	58
Male	34	54	42

Reporting group values	HIV- (3+0) Group	HIV-(2+1) Group	Total
Number of subjects	100	100	484
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	100	100	484
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: weeks			
arithmetic mean	6.1	6.1	
standard deviation	± 0.35	± 0.29	-
Gender categorical Units: Subjects			
Female	50	47	251
Male	50	53	233

End points

End points reporting groups

Reporting group title	HIV+/+ Group

Reporting group description:

Infants born from a HIV positive mother and confirmed as HIV infected. Subjects received 3 primary doses (at 6, 10 and 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 and 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 and 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age and 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered intramuscularly in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix given orally.

Reporting group title	HIV+/- Group

Reporting group description:

Infants born from a HIV positive mother and confirmed as HIV exposed uninfected.Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV-(3+1) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV- (3+0) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 3 primary doses of Synflorix vaccine (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix™-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV-(2+1) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 2 primary doses (at 6 & 14 weeks of age at study Months 0 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Primary: Number of Subjects With Anti-pneumococcal Vaccine Serotype Antibody Concentrations Equal to or Above 0.20 Microgram Per Millilitre (µg/mL)

End point title	Number of Subjects With Anti-pneumococcal Vaccine Serotype Antibody Concentrations Equal to or Above 0.20 Microgram Per Millilitre (µg/mL)[1]

End point description:

Pneumococcal vaccine serotypes assessed were 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Primary

End point timeframe:

1 month following primary immunization (post-Dose 3 at Month 3 for the HIV+/+ Group, HIV+/- Group, HIV- (3+1) Group, HIV- (3+0) Group and post-Dose 2 at Month 3 for the HIV- (2+1) Group)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	91	93	94
Units: Subject				
Anti-1 (N=70,91,93,94,97)	69	90	93	94
Anti-4 (N=70,91,93,93,97)	69	90	93	93
Anti-5 (N=70,91,93,94,97)	70	90	93	94
Anti-6B (N=70,91,93,93,97)	61	80	74	83
Anti-7F (N=70,91,93,94,97)	69	90	93	94
Anti-9V (N=70,91,93,94,97)	68	90	93	94
Anti-14 (N=70,91,93,93,97)	69	90	93	93
Anti-18C (N=69,91,93,94,97)	69	90	93	94
Anti-19F (N=70,91,93,93,96)	68	90	93	93
Anti-23F (N=70,91,93,93,97)	63	84	83	84

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: Subject				
Anti-1 (N=70,91,93,94,97)	96			
Anti-4 (N=70,91,93,93,97)	96			
Anti-5 (N=70,91,93,94,97)	95			
Anti-6B (N=70,91,93,93,97)	80			
Anti-7F (N=70,91,93,94,97)	96			
Anti-9V (N=70,91,93,94,97)	92			
Anti-14 (N=70,91,93,93,97)	95			
Anti-18C (N=69,91,93,94,97)	95			

Anti-19F (N=70,91,93,93,96)	94			
Anti-23F (N=70,91,93,93,97)	84			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Any and Severe (Grade 3) Solicited Local Adverse Events (AEs)

End point title	Number of Subjects With Any and Severe (Grade 3) Solicited Local Adverse Events (AEs)

End point description:

Solicited local AEs assessed were pain, redness and swelling. Any = incidence of any local symptom regardless of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling above 30 millimeter.
The Total Vaccinated cohort included all subjects who received at least one vaccine dose administration, with analysis done solely on subjects for whom post-vaccination results about solicited symptoms were available.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-primary vaccination period across doses

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	83	101	98	98
Units: Subjects				
Any pain	73	93	92	95
Grade 3 pain	18	18	28	42
Any redness	62	80	83	83
Redness > 30 mm	14	10	17	20
Any swelling	67	83	84	91
Swelling > 30 mm	23	32	41	44

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: Subjects				
Any pain	97			
Grade 3 pain	34			
Any redness	84			
Redness > 30 mm	14			
Any swelling	84			
Swelling > 30 mm	31			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Any, Severe (Grade 3) and Related Solicited General Adverse Events (AEs)

End point title	Number of Subjects with Any, Severe (Grade 3) and Related Solicited General Adverse Events (AEs)

End point description:

General AEs = diarrhoea, drowsiness, irritability, loss of appetite, vomiting and fever (axillary greater than or equal to [≥] 37.5 degrees Celsius). Any= Incidence of any symptom regardless of intensity grade or relationship to vaccination. Grade 3: drowsiness = prevented normal activity. Irritability = crying that could not be comforted/ prevented normal activity. Loss of appetite = not eating at all. Diarrhoea: ≥ 6 looser than normal stools/day. Vomiting: ≥ 3 episodes of vomiting/day. Fever = greater than (>) 39.5°C Related = symptom assessed by the investigator as related to the vaccination.
The Total Vaccinated cohort included all subjects who received at least one vaccine dose administration, with analysis done solely on subjects for whom post-vaccination results about solicited symptoms were available.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-primary vaccination period across doses

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	83	101	98	98
Units: Subjects				
Any diarrhoea	8	5	12	10
Grade 3 diarrhoea	2	0	3	3
Related diarrhoea	8	5	11	9
Any drowsiness	49	62	70	70
Grade 3 drowsiness	1	6	5	7
Related drowsiness	47	58	67	66
Fever (axillary) > 39.5°C	0	0	2	0
Related fever	33	30	38	27
Any irritability	63	84	89	89
Grade 3 irritability	6	10	19	13
Related irritability	62	80	86	83
Any loss of appetite	36	53	56	57
Grade 3 loss of appetite	0	1	2	2
Related loss of appetite	35	47	53	53
Any vomiting	17	19	15	18
Grade 3 vomiting	3	3	4	5
Related vomiting	16	16	14	13
Fever (axillary) ≥ 37.5°C	38	36	41	28

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: Subjects				
Any diarrhoea	5			
Grade 3 diarrhoea	2			
Related diarrhoea	5			
Any drowsiness	68			
Grade 3 drowsiness	8			
Related drowsiness	63			
Fever (axillary) > 39.5°C	0			
Related fever	25			
Any irritability	91			
Grade 3 irritability	15			
Related irritability	85			
Any loss of appetite	62			
Grade 3 loss of appetite	5			
Related loss of appetite	58			
Any vomiting	23			
Grade 3 vomiting	2			
Related vomiting	17			
Fever (axillary) ≥ 37.5°C	28			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Any and Severe (Grade 3) Solicited Local Adverse Events (AEs)

End point title	Number of Subjects With Any and Severe (Grade 3) Solicited Local Adverse Events (AEs)[2]

End point description:

Solicited local AEs assessed were pain, redness and swelling. Any = incidence of any local symptom regardless of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling > 30 millimeter.
The Total Vaccinated cohort included all subjects who received at least one vaccine dose administration, with analysis done solely on subjects for whom post-vaccination results about solicited symptoms were available.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) period following booster vaccination with Synflorix vaccine

Notes:

[2] - 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: This endpoint is only reporting values for the arms that received Synflorix booster vaccination.

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV-(2+1) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	95	96	96
Units: Subjects				
Any pain	40	58	62	60
Grade 3 pain	2	1	2	6
Any redness	25	31	39	45
Redness > 30 mm	5	1	3	0
Any swelling	28	39	38	53
Swelling > 30 mm	5	4	8	10

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Any, Severe (Grade 3) and Related Solicited General Adverse Events (AEs)

End point title	Number of Subjects With Any, Severe (Grade 3) and Related Solicited General Adverse Events (AEs)[3]

End point description:

Solicited general AEs = drowsiness, irritability, loss of appetite and fever (axillary ≥ 37.5 degrees Celsius). Any= Incidence of any symptom regardless of intensity grade or relationship to vaccination. Grade 3: drowsiness = prevented normal activity. Irritability = crying that could not be comforted/ prevented normal activity. Loss of appetite = not eating at all. Fever = temperature > 39.5°C. Related = symptom assessed by the investigator as related to the vaccination.
The Total Vaccinated cohort included all subjects who received at least one vaccine dose administration, with analysis done solely on subjects for whom post-vaccination results about solicited symptoms were available.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) period following booster vaccination with Synflorix vaccine

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the arms that received Synflorix booster vaccination.

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV-(2+1) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	95	96	96
Units: Subjects				
Any drowsiness	17	28	34	33
Grade 3 drowsiness	2	0	1	1
Related drowsiness	16	27	31	32
Fever > 39.5°C	0	0	0	0
Related fever	8	10	7	10
Any irritability	25	35	31	43
Grade 3 irritability	4	1	1	1
Related irritability	24	35	31	42
Any loss of appetite	17	23	29	37
Grade 3 loss of appetite	0	0	1	2

Related loss of appetite	16	23	29	33
Fever ≥ 37.5°C	9	11	7	11

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Unsolicited AEs

End point title	Number of Subjects With Unsolicited AEs

End point description:

An unsolicited adverse event is any adverse event (i.e. any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with use of a medicinal product, whether or not considered related to the medicinal product) reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms.
The Total Vaccinated cohort included all subjects with at least one vaccine dose administration documented.

End point type	Secondary

End point timeframe:

Within the 31-day (Days 0-30) post-primary vaccination period

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	83	101	100	100
Units: Subjects				
Any AE	73	92	93	90

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: Subjects				
Any AE	97			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Unsolicited AEs

End point title	Number of Subjects With Unsolicited AEs[4]

End point description:

An unsolicited adverse event is any adverse event (i.e. any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with use of a medicinal product, whether or not considered related to the medicinal product) reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms.
The Total Vaccinated cohort included all subjects with at least one vaccine dose administration documented.

End point type	Secondary

End point timeframe:

Within the 31-day (Days 0-30) post Synflorix booster vaccination period

Notes:

[4] - 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: This endpoint is only reporting values for the arms that received Synflorix booster vaccination.

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV-(2+1) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	76	96	98	98
Units: Subjects				
Any AEs	35	47	50	44

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Adverse Events (SAEs)

End point title	Number of Subjects With Serious Adverse Events (SAEs)

End point description:

SAEs assessed include medical occurrences that results in death, are life threatening, require hospitalization or prolongation of hospitalization, results in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subjects.
The Total Vaccinated cohort included all subjects with at least one vaccine dose administration documented.

End point type	Secondary

End point timeframe:

From study start at Month 0 (6 weeks of age and above) up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	83	101	100	100
Units: Subjects				
Any SAEs	31	25	20	15

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: Subjects				
Any SAEs	20			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of antibodies against Vaccine Pneumococcal Serotypes

End point title	Concentrations of antibodies against Vaccine Pneumococcal Serotypes

End point description:

Concentrations were given in microgram per millilitre (µg/mL) and were expressed in geometric mean antibody concentrations. Pneumococcal vaccine serotypes assessed were 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F. Data were collected post-Dose 3 at Month 3 and post-Dose 4 at Month 9 for the HIV+/+, HIV+/- and HIV- (3+1) groups, post-Dose 3 at Month 3 and at Month 9 for HIV- (3+0) group, and post-Dose 2 at Month 3 and post-Dose 3 at Month 9 for the HIV- (2+1) Group. The cut-off of the assay is 0.05 µg/mL.
The According-To-Protocol (ATP) cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

At Month 3 and Month 9

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	91	93	94
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1 [Month 3] (N=70,91,93,94,97)	4 (3.3 to 4.84)	3.85 (3.26 to 4.55)	3.36 (2.91 to 3.88)	4.65 (3.91 to 5.53)
Anti-1 [Month 9] (N=66,89,93,93,97)	6.64 (5.22 to 8.46)	8.64 (7.09 to 10.53)	5.38 (4.47 to 6.48)	0.72 (0.58 to 0.88)
Anti-4 [Month 3] (N=70,91,93,93,97)	3.67 (2.81 to 4.8)	3.14 (2.6 to 3.8)	2.71 (2.28 to 3.21)	3.77 (3.09 to 4.6)
Anti-4 [Month 9] (N=66,89,93,93,97)	6.97 (5.72 to 8.5)	8.04 (6.69 to 9.68)	6.07 (5.09 to 7.24)	1.07 (0.86 to 1.34)
Anti-5 [Month 3] (N=70,91,93,94,97)	4.99 (4 to 6.23)	4.79 (3.96 to 5.79)	4.41 (3.79 to 5.13)	5.71 (4.84 to 6.75)
Anti-5 [Month 9] (N=66,89,93,93,97)	7.86 (6.25 to 9.89)	9.48 (7.84 to 11.46)	8.05 (6.7 to 9.66)	1.44 (1.16 to 1.77)
Anti-6B [Month 3] (N=70,91,93,93,97)	1 (0.73 to 1.38)	0.94 (0.71 to 1.24)	0.65 (0.5 to 0.86)	1.06 (0.81 to 1.39)
Anti-6B [Month 9] (N=66,89,93,93,97)	2.26 (1.72 to 2.98)	2.56 (2.01 to 3.25)	2.05 (1.57 to 2.68)	0.93 (0.75 to 1.15)

Anti-7F [Month 3] (N=70,91,93,94,97)	4.95 (3.82 to 6.41)	3.69 (3.08 to 4.41)	3.62 (3.12 to 4.19)	4.77 (4.06 to 5.6)
Anti-7F [Month 9] (N=66,89,93,93,97)	9.92 (7.89 to 12.47)	11.04 (9.29 to 13.11)	8.98 (7.63 to 10.56)	1.78 (1.49 to 2.13)
Anti-9V [Month 3] (N=70,91,93,94,97)	4.53 (3.39 to 6.05)	4.25 (3.49 to 5.16)	3.04 (2.51 to 3.69)	5.13 (4.35 to 6.04)
Anti-9V [Month 9] (N=66,89,93,93,97)	10.09 (7.64 to 13.32)	10.89 (9.11 to 13.03)	9.55 (8.06 to 11.31)	1.96 (1.58 to 2.43)
Anti-14 [Month 3] (N=70,91,93,93,97)	7.25 (5.37 to 9.81)	6.77 (5.43 to 8.44)	3.85 (3.18 to 4.68)	5.27 (4.31 to 6.45)
Anti-14 [Month 9] (N=66,89,93,93,97)	11.5 (9.17 to 14.41)	10.58 (8.6 to 13)	7.33 (5.94 to 9.04)	2.6 (2.01 to 3.37)
Anti-18C [Month 3] (N=69,91,93,94,97)	9.55 (7.19 to 12.67)	9.48 (7.41 to 12.13)	10.08 (8.25 to 12.31)	13.2 (10.31 to 16.9)
Anti-18C [Month 9] (N=66,89,93,93,97)	20.26 (16.13 to 25.45)	19.67 (15.89 to 24.35)	25.47 (21.75 to 29.83)	3.3 (2.55 to 4.27)
Anti-19F [Month 3] (N=70,91,93,93,96)	5.7 (4.06 to 8.02)	11.15 (8.88 to 13.99)	8.75 (7.37 to 10.38)	10.93 (9.2 to 12.99)
Anti-19F [Month 9] (N=66,89,93,93,97)	8 (5.86 to 10.92)	12.46 (10.47 to 14.84)	8.88 (7.37 to 10.69)	2.6 (2.03 to 3.31)
Anti-23F [Month 3] (N=70,91,93,93,97)	1.71 (1.23 to 2.37)	1.52 (1.14 to 2.01)	0.92 (0.72 to 1.19)	1.59 (1.21 to 2.09)
Anti-23F [Month 9] (N=66,89,93,93,97)	4 (2.69 to 5.93)	5.9 (4.37 to 7.96)	3.83 (2.84 to 5.15)	0.92 (0.68 to 1.23)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1 [Month 3] (N=70,91,93,94,97)	3.33 (2.85 to 3.88)			
Anti-1 [Month 9] (N=66,89,93,93,97)	5.14 (4.42 to 5.97)			
Anti-4 [Month 3] (N=70,91,93,93,97)	2.28 (1.9 to 2.75)			
Anti-4 [Month 9] (N=66,89,93,93,97)	4.92 (4.16 to 5.81)			
Anti-5 [Month 3] (N=70,91,93,94,97)	3.45 (2.85 to 4.16)			
Anti-5 [Month 9] (N=66,89,93,93,97)	6.96 (5.89 to 8.22)			
Anti-6B [Month 3] (N=70,91,93,93,97)	0.57 (0.45 to 0.73)			
Anti-6B [Month 9] (N=66,89,93,93,97)	1.98 (1.62 to 2.42)			
Anti-7F [Month 3] (N=70,91,93,94,97)	2.72 (2.3 to 3.22)			
Anti-7F [Month 9] (N=66,89,93,93,97)	6.47 (5.59 to 7.5)			
Anti-9V [Month 3] (N=70,91,93,94,97)	2.05 (1.61 to 2.61)			
Anti-9V [Month 9] (N=66,89,93,93,97)	6.51 (5.12 to 8.3)			
Anti-14 [Month 3] (N=70,91,93,93,97)	2.51 (1.98 to 3.19)			

Anti-14 [Month 9] (N=66,89,93,93,97)	5.08 (4.03 to 6.41)			
Anti-18C [Month 3] (N=69,91,93,94,97)	8.65 (6.44 to 11.6)			
Anti-18C [Month 9] (N=66,89,93,93,97)	32.29 (26.43 to 39.45)			
Anti-19F [Month 3] (N=70,91,93,93,96)	6.9 (5.62 to 8.48)			
Anti-19F [Month 9] (N=66,89,93,93,97)	9.47 (7.42 to 12.07)			
Anti-23F [Month 3] (N=70,91,93,93,97)	0.97 (0.74 to 1.27)			
Anti-23F [Month 9] (N=66,89,93,93,97)	3.4 (2.67 to 4.33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Vaccine Pneumococcal Serotypes

End point title	Concentrations of Antibodies Against Vaccine Pneumococcal Serotypes

End point description:

Concentrations were given in microgram per millilitre (µg/mL) and were expressed in geometric mean antibody concentrations. Pneumococcal vaccine serotypes assessed were 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F. Data were collected post-Dose 4 at Month 23 for the HIV+/+, HIV+/- and HIV- (3+1) groups and post-Dose 3 at Month 23 for HIV- (3+0) and HIV- (2+1) groups. The cut-off of the assay is 0.05 µg/mL.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

Up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	86	92	91
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1 (N=63,86,92,90,97)	0.53 (0.35 to 0.8)	0.74 (0.57 to 0.95)	0.42 (0.34 to 0.53)	0.28 (0.22 to 0.37)
Anti-4 (N=63,86,92,91,97)	0.56 (0.38 to 0.8)	0.57 (0.46 to 0.71)	0.44 (0.35 to 0.57)	0.33 (0.25 to 0.44)
Anti-5 (N=63,86,92,90,97)	0.79 (0.55 to 1.15)	0.77 (0.61 to 0.97)	0.72 (0.57 to 0.92)	0.45 (0.36 to 0.57)
Anti-6B (N=63,86,92,91,97)	0.67 (0.42 to 1.06)	0.73 (0.56 to 0.97)	0.6 (0.47 to 0.77)	0.76 (0.56 to 1.03)
Anti-7F (N=63,86,92,91,97)	1.25 (0.9 to 1.75)	1.16 (0.96 to 1.39)	1.08 (0.92 to 1.27)	0.67 (0.54 to 0.83)

Anti-9V (N=63,86,92,91,97)	1.15 (0.77 to 1.71)	1.3 (1.04 to 1.63)	1.05 (0.86 to 1.28)	0.85 (0.68 to 1.06)
Anti-14 (N=63,86,92,91,97)	2.62 (2.02 to 3.4)	2.09 (1.69 to 2.58)	1.32 (1.07 to 1.64)	1.24 (0.96 to 1.61)
Anti-18C (N=63,86,92,91,97)	2.02 (1.41 to 2.89)	1.6 (1.22 to 2.09)	1.93 (1.58 to 2.35)	0.8 (0.63 to 1.01)
Anti-19F (N=63,86,92,91,97)	2.01 (1.32 to 3.08)	2.28 (1.72 to 3.02)	2.53 (1.91 to 3.34)	1.59 (1.15 to 2.2)
Anti-23F (N=63,86,92,90,97)	0.73 (0.49 to 1.09)	0.85 (0.63 to 1.14)	0.51 (0.39 to 0.67)	0.53 (0.38 to 0.73)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1 (N=63,86,92,90,97)	0.33 (0.26 to 0.41)			
Anti-4 (N=63,86,92,91,97)	0.34 (0.27 to 0.43)			
Anti-5 (N=63,86,92,90,97)	0.52 (0.43 to 0.64)			
Anti-6B (N=63,86,92,91,97)	0.57 (0.44 to 0.74)			
Anti-7F (N=63,86,92,91,97)	0.84 (0.7 to 1)			
Anti-9V (N=63,86,92,91,97)	0.8 (0.64 to 1)			
Anti-14 (N=63,86,92,91,97)	1.06 (0.83 to 1.36)			
Anti-18C (N=63,86,92,91,97)	2.44 (1.97 to 3.02)			
Anti-19F (N=63,86,92,91,97)	2.22 (1.74 to 2.84)			
Anti-23F (N=63,86,92,90,97)	0.52 (0.37 to 0.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic Titers against Vaccine Pneumococcal Serotypes

End point title	Opsonophagocytic Titers against Vaccine Pneumococcal Serotypes

End point description:

Pneumococcal vaccine serotypes assessed were 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F. Data were collected post-Dose 3 at Month 3 and post-Dose 4 at Month 9 for the HIV+/+, HIV+/- and HIV- (3+1) groups,post-Dose 3 at Month 3 and at Month 9 for HIV- (3+0) group, and post-Dose 2 at Month 3 and post-Dose 3 at Month 9 for the HIV- (2+1) Group. Streptococcus pneumoniae opsonophagocytic activity was measured by a killing-assay using a HL 60 cell line. The results are presented as the dilution of serum (opsonic titer) able to sustain 50% killing of live pneumococci under the assay conditions. The cut-off of the assay is an opsonic titer of 8.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay

results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

At Month 3 and Month 9

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	91	93	92
Units: Titers				
geometric mean (confidence interval 95%)				
Opsono-1 [Month 3] (N=68,91,93,92,96)	139.7 (85.2 to 229)	147.6 (102.9 to 211.7)	127.2 (86.2 to 187.8)	268.7 (196.7 to 366.9)
Opsono-1 [Month 9] (N=63,85,90,89,94)	1061.5 (680.5 to 1655.8)	1377.8 (984.9 to 1927.4)	1014.8 (768.4 to 1340.3)	23.5 (16.1 to 34.4)
Opsono-4 [Month 3] (N=67,91,93,92,96)	671.6 (430.7 to 1047.5)	1518.1 (1149.7 to 2004.4)	1711.9 (1367.7 to 2142.9)	1890.6 (1547.2 to 2310.2)
Opsono-4 [Month 9] (N=62,86,90,87,95)	2034.2 (1593.5 to 2596.9)	3259 (2579.2 to 4117.9)	2484.7 (1919 to 3217.1)	112.3 (70.8 to 178.1)
Opsono-5 [Month 3] (N=68,91,93,92,96)	105.7 (73.8 to 151.4)	128.6 (97.5 to 169.5)	107.4 (81.8 to 141)	189.2 (147 to 243.5)
Opsono-5 [Month 9] (N=63,85,90,90,94)	540.4 (366.4 to 796.9)	531.1 (397.3 to 710)	630.2 (447.5 to 887.7)	30.5 (21.8 to 42.5)
Opsono-6B [Month 3] (N=68,90,92,91,92)	239.7 (123 to 467.4)	480.5 (282.1 to 818.5)	499.5 (286.1 to 872.2)	1213.7 (808.2 to 1822.6)
Opsono-6B [Month 9] (N=60,84,88,86,94)	853 (467.8 to 1555.3)	986.6 (667.6 to 1457.9)	1047.2 (679.3 to 1614.4)	261.5 (161 to 424.7)
Opsono-7F [Month 3] (N=68,90,92,92,95)	4025.2 (2609.7 to 6208.4)	10158.3 (7772 to 13277.2)	5910.5 (4696.9 to 7437.6)	6834.5 (5280.8 to 8845.4)
Opsono-7F [Month 9] (N=63,85,88,90,95)	10656.1 (7729.9 to 14690)	18816.6 (14352.2 to 24669.7)	12108.8 (9922.2 to 14777.4)	2741.1 (2173.7 to 3456.5)
Opsono-9V [Month 3] (N=68,90,93,92,96)	1197.2 (796.2 to 1800.1)	1736.5 (1224.1 to 2463.5)	1672.2 (1243.6 to 2248.4)	2216 (1760.9 to 2788.8)
Opsono-9V [Month 9] (N=64,86,91,90,94)	2436.8 (1736.5 to 3419.7)	3215.4 (2515.8 to 4109.6)	4250.1 (3493.4 to 5170.8)	492.3 (351.2 to 690.1)
Opsono-14 [Month 3] (N=68,90,92,92,95)	2656.2 (1686.7 to 4183)	3175.1 (2472.8 to 4077)	1902.7 (1300.9 to 2782.9)	2205 (1648.8 to 2948.7)
Opsono-14 [Month 9] (N=65,87,89,87,94)	2205.9 (1570.2 to 3099)	2374.3 (1923.2 to 2931.2)	2180 (1781.9 to 2667)	280 (183 to 428.6)
Opsono-18C [Month 3] (N=68,91,91,92,93)	438.7 (284.1 to 677.3)	575.9 (442.9 to 748.8)	1046.9 (802.6 to 1365.5)	1203.2 (981.2 to 1475.4)
Opsono-18C [Month 9] (N=62,85,90,90,93)	1039.3 (770.2 to 1402.3)	1036.5 (800.1 to 1342.7)	1344.4 (1074.6 to 1681.9)	64.5 (44.1 to 94.3)
Opsono-19F [Month 3] (N=68,91,92,92,95)	228.6 (132.5 to 394.4)	590.3 (418.9 to 831.6)	511.9 (394.1 to 664.9)	649.3 (481.1 to 876.2)
Opsono-19F [Month 9] (N=61,86,89,88,94)	488.2 (275.3 to 865.9)	1357.5 (976.2 to 1887.8)	730.8 (516.5 to 1034.1)	46.8 (31.6 to 69.5)

Opsono-23F [Month 3] (N=68,89,88,92,91)	338 (174.1 to 656.2)	769.6 (451.1 to 1312.9)	864.1 (511.2 to 1460.6)	1107 (683 to 1794)
Opsono-23F [Month 9] (N=63,87,90,86,95)	1327.4 (736.2 to 2393.5)	2120.7 (1359.4 to 3308.1)	2144.8 (1312.5 to 3504.8)	83.6 (47.2 to 148)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	96			
Units: Titers				
geometric mean (confidence interval 95%)				
Opsono-1 [Month 3] (N=68,91,93,92,96)	160.6 (117.8 to 218.8)			
Opsono-1 [Month 9] (N=63,85,90,89,94)	1003.6 (763.2 to 1319.8)			
Opsono-4 [Month 3] (N=67,91,93,92,96)	774.8 (596.7 to 1006)			
Opsono-4 [Month 9] (N=62,86,90,87,95)	1717.6 (1406 to 2098.2)			
Opsono-5 [Month 3] (N=68,91,93,92,96)	105.7 (81.6 to 136.8)			
Opsono-5 [Month 9] (N=63,85,90,90,94)	472.7 (343.5 to 650.5)			
Opsono-6B [Month 3] (N=68,90,92,91,92)	361.2 (221.8 to 588.2)			
Opsono-6B [Month 9] (N=60,84,88,86,94)	945.9 (640 to 1398.2)			
Opsono-7F [Month 3] (N=68,90,92,92,95)	2650 (2002 to 3507.9)			
Opsono-7F [Month 9] (N=63,85,88,90,95)	6029.3 (4760.9 to 7635.6)			
Opsono-9V [Month 3] (N=68,90,93,92,96)	1068.2 (759.2 to 1503)			
Opsono-9V [Month 9] (N=64,86,91,90,94)	2572.5 (1890.3 to 3500.8)			
Opsono-14 [Month 3] (N=68,90,92,92,95)	380.9 (228.1 to 636)			
Opsono-14 [Month 9] (N=65,87,89,87,94)	1152.9 (910.6 to 1459.6)			
Opsono-18C [Month 3] (N=68,91,91,92,93)	1052.3 (777.7 to 1423.8)			
Opsono-18C [Month 9] (N=62,85,90,90,93)	1441.3 (1111.7 to 1868.5)			
Opsono-19F [Month 3] (N=68,91,92,92,95)	275.9 (193.4 to 393.5)			
Opsono-19F [Month 9] (N=61,86,89,88,94)	630.3 (422.9 to 939.5)			
Opsono-23F [Month 3] (N=68,89,88,92,91)	509.6 (306.8 to 846.6)			
Opsono-23F [Month 9] (N=63,87,90,86,95)	1557.2 (1012.2 to 2395.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic Titers Against Vaccine Pneumococcal Serotypes

End point title	Opsonophagocytic Titers Against Vaccine Pneumococcal Serotypes

End point description:

Pneumococcal vaccine serotypes assessed were 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F. Data were collected post-Dose 4 at Month 23 for the HIV+/+, HIV+/- and HIV- (3+1) groups and post-Dose 3 at Month 23 for HIV- (3+0) and HIV- (2+1) groups. Streptococcus pneumoniae opsonophagocytic activity was measured by a killing-assay using a HL 60 cell line. The results are presented as the dilution of serum (opsonic titer) able to sustain 50% killing of live pneumococci under the assay conditions. The cut-off of the assay is an opsonic titer of 8.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

Up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	84	89	86
Units: Titers				
geometric mean (confidence interval 95%)				
Opsono-1 (N=59,84,89,85,91)	36.7 (19.6 to 68.9)	28.1 (17.4 to 45.4)	22.8 (14.9 to 34.9)	12.3 (8.2 to 18.6)
Opsono-4 (N=53,74,82,79,83)	76.6 (36.8 to 159.5)	141.7 (79.2 to 253.5)	125.5 (69.1 to 228.2)	21.6 (12.4 to 37.5)
Opsono-5 (N=57,82,88,86,89)	22.5 (13.7 to 37)	19.1 (13.9 to 26.2)	19.5 (14.2 to 26.7)	8.6 (6.5 to 11.3)
Opsono-6B (N=54,81,80,79,83)	100 (48.8 to 204.7)	75.5 (44.2 to 128.8)	116.6 (63.7 to 213.3)	87.2 (48.2 to 157.7)
Opsono-7F (N=55,80,81,77,81)	6367.5 (4511.3 to 8987.6)	7396.6 (5736.2 to 9537.6)	6365 (5177.2 to 7825.4)	5601.1 (4334.9 to 7237.3)
Opsono-9V (N=53,80,85,84,89)	507.6 (315.2 to 817.5)	598.6 (396.9 to 902.7)	1060.7 (761.2 to 1478.1)	412.3 (267.4 to 635.9)
Opsono-14 (N=56,79,84,76,80)	452 (270.6 to 755)	472.8 (305.1 to 732.6)	362.3 (229.7 to 571.6)	361.5 (213.2 to 613.2)
Opsono-18C (N=56,71,80,83,78)	21.1 (13 to 34.4)	26.7 (17.1 to 41.6)	48.7 (30.4 to 78.1)	9.8 (6.6 to 14.5)
Opsono-19F (N=55,74,86,82,85)	41.8 (23.5 to 74.4)	73.2 (47.1 to 114)	52.5 (33.2 to 83.1)	28.2 (17.8 to 44.6)

Opsono-23F (N=53,78,80,78,80)	97.6 (38.2 to 249.6)	154.8 (71.7 to 334.2)	69.7 (31.7 to 153.1)	92.7 (40.7 to 211.2)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	91			
Units: Titers				
geometric mean (confidence interval 95%)				
Opsono-1 (N=59,84,89,85,91)	13.9 (9.8 to 19.7)			
Opsono-4 (N=53,74,82,79,83)	58.8 (33 to 105)			
Opsono-5 (N=57,82,88,86,89)	13.3 (10.2 to 17.3)			
Opsono-6B (N=54,81,80,79,83)	55.9 (32 to 97.7)			
Opsono-7F (N=55,80,81,77,81)	5859.9 (4371.4 to 7855.2)			
Opsono-9V (N=53,80,85,84,89)	465.7 (318.2 to 681.6)			
Opsono-14 (N=56,79,84,76,80)	185.2 (105.8 to 324.1)			
Opsono-18C (N=56,71,80,83,78)	41.6 (27.3 to 63.3)			
Opsono-19F (N=55,74,86,82,85)	47.6 (30.1 to 75.1)			
Opsono-23F (N=53,78,80,78,80)	103.5 (47 to 227.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies against Cross-reactive Pneumococcal Serotypes 6A and 19A

End point title	Concentrations of Antibodies against Cross-reactive Pneumococcal Serotypes 6A and 19A

End point description:

Concentrations were given in microgram per millilitre (µg/mL) and were expressed in geometric mean antibody concentrations. Cross-reactive pneumococcal vaccine serotypes assessed were 6A and 19A. Data were collected post-Dose 3 at Month 3 and post-Dose 4 at Month 9 for the HIV+/+, HIV+/- and HIV- (3+1) groups,post-Dose 3 at Month 3 and at Month 9 for HIV- (3+0) group, and post-Dose 2 at Month 3 and post-Dose 3 at Month 9 for the HIV- (2+1) Group. The cut-off of the assay is 0.05 µg/mL. The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

At Month 3 and Month 9

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	91	93	93
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-6A [Month 3] (N=70,91,93,93,97)	0.15 (0.12 to 0.19)	0.12 (0.1 to 0.15)	0.12 (0.1 to 0.15)	0.13 (0.11 to 0.16)
Anti-6A [Month 9] (N=66,89,93,93,97)	0.48 (0.34 to 0.67)	0.58 (0.43 to 0.77)	0.36 (0.27 to 0.49)	0.21 (0.15 to 0.28)
Anti-19A [Month 3] (N=69,91,93,92,97)	0.16 (0.12 to 0.23)	0.28 (0.21 to 0.36)	0.2 (0.16 to 0.25)	0.29 (0.23 to 0.38)
Anti-19A [Month 9] (N=66,89,93,93,97)	0.99 (0.61 to 1.61)	1.48 (1.06 to 2.08)	0.78 (0.57 to 1.07)	0.26 (0.19 to 0.37)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-6A [Month 3] (N=70,91,93,93,97)	0.11 (0.09 to 0.13)			
Anti-6A [Month 9] (N=66,89,93,93,97)	0.36 (0.28 to 0.47)			
Anti-19A [Month 3] (N=69,91,93,92,97)	0.25 (0.2 to 0.32)			
Anti-19A [Month 9] (N=66,89,93,93,97)	1.04 (0.72 to 1.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Cross-reactive Pneumococcal Serotypes 6A and 19A

End point title	Concentrations of Antibodies Against Cross-reactive Pneumococcal Serotypes 6A and 19A

End point description:

Concentrations were given in microgram per millilitre (µg/mL) and were expressed in geometric mean antibody concentrations. Cross-reactive pneumococcal vaccine serotypes assessed were 6A and 19A. Data were collected post-Dose 4 at Month 23 for the HIV+/+, HIV+/- and HIV- (3+1) groups and post-Dose 3 at Month 23 for HIV- (3+0) and HIV- (2+1) groups. The cut-off of the assay is 0.05 µg/mL. The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

Up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	86	92	91
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-6A (N=63,86,92,91,97)	0.23 (0.14 to 0.38)	0.25 (0.17 to 0.35)	0.2 (0.15 to 0.27)	0.25 (0.18 to 0.36)
Anti-19A (N=63,86,92,89,97)	0.45 (0.26 to 0.76)	0.47 (0.31 to 0.72)	0.53 (0.35 to 0.8)	0.41 (0.28 to 0.6)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-6A (N=63,86,92,91,97)	0.19 (0.14 to 0.26)			
Anti-19A (N=63,86,92,89,97)	0.58 (0.41 to 0.83)			

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic Titers against Cross-reactive Pneumococcal Serotypes 6A and 19A

End point title	Opsonophagocytic Titers against Cross-reactive Pneumococcal Serotypes 6A and 19A

End point description:

Cross-reactive pneumococcal vaccine serotypes assessed were 6A and 19A. Data were collected post-Dose 3 at Month 3 and post-Dose 4 at Month 9 for the HIV+/+, HIV+/- and HIV- (3+1) groups,post-Dose 3 at Month 3 and at Month 9 for HIV- (3+0) group, and post-Dose 2 at Month 3 and post-Dose 3 at Month 9 for the HIV- (2+1) Group. Streptococcus pneumoniae opsonophagocytic activity was measured by a killing-assay using a HL 60 cell line. The results are presented as the dilution of serum (opsonic titer) able to sustain 50% killing of live pneumococci under the assay conditions. The cut-off of the assay is an opsonic titer of 8.
ATP cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

At Month 3 and Month 9

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	91	93	91
Units: Titers				
geometric mean (confidence interval 95%)				
Opsono -6A [Month 3] (N=67,91,89,91,95)	7.7 (5.2 to 11.5)	11.5 (7.4 to 17.9)	12.1 (7.8 to 18.9)	13.8 (9.1 to 20.9)
Opsono -6A [Month 9] (N=64,86,83,86,94)	26.4 (14.7 to 47.3)	38.6 (22.2 to 67)	40.4 (22.9 to 71.4)	9.5 (6.5 to 14)
Opsono -19A [Month 3] (N=66,91,93,90,95)	9.5 (6.4 to 14)	15.2 (10.4 to 22.2)	10.6 (7.7 to 14.7)	14.2 (9.7 to 20.8)
Opsono -19A [Month 9] (N=63,86,89,89,92)	42 (24.8 to 71.2)	101.8 (63.9 to 162.3)	38.3 (24.1 to 60.9)	7.9 (5.7 to 10.9)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	95			
Units: Titers				
geometric mean (confidence interval 95%)				
Opsono -6A [Month 3] (N=67,91,89,91,95)	8.1 (5.8 to 11.3)			
Opsono -6A [Month 9] (N=64,86,83,86,94)	42.2 (25.5 to 69.9)			
Opsono -19A [Month 3] (N=66,91,93,90,95)	7.8 (5.9 to 10.2)			
Opsono -19A [Month 9] (N=63,86,89,89,92)	36.1 (22.3 to 58.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic Titers against Cross-reactive Pneumococcal Serotypes 6A and 19A

End point title	Opsonophagocytic Titers against Cross-reactive Pneumococcal Serotypes 6A and 19A

End point description:

Cross-reactive pneumococcal vaccine serotypes assessed were 6A and 19A. Data were collected post-Dose 4 at Month 23 for the HIV+/+, HIV+/- and HIV- (3+1) groups and post-Dose 3 at Month 23 for HIV- (3+0) and HIV- (2+1) groups. Streptococcus pneumoniae opsonophagocytic activity was measured by a killing-assay using a HL 60 cell line. The results are presented as the dilution of serum (opsonic titer) able to sustain 50% killing of live pneumococci under the assay conditions. The cut-off of the assay is an opsonic titer of 8.

The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

Up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	79	80	82
Units: Titers				
geometric mean (confidence interval 95%)				
Opsono-6A (N=53,79,79,79,79)	14.2 (7.5 to 27.2)	15.7 (9.4 to 26.2)	20.5 (12.2 to 34.3)	15.3 (8.5 to 27.5)
Opsono-19A (N=56,79,80,82,81)	19.9 (11.4 to 34.8)	15.8 (10 to 24.8)	25.1 (15.1 to 41.9)	14.5 (9.4 to 22.6)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: Titers				
geometric mean (confidence interval 95%)				
Opsono-6A (N=53,79,79,79,79)	19 (11.4 to 31.9)			
Opsono-19A (N=56,79,80,82,81)	16.8 (10.9 to 26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Protein D (PD) by ELISA

End point title	Concentrations of Antibodies Against Protein D (PD) by ELISA

End point description:

Concentrations of antibodies are presented as GMCs expressed as ELISA units per milliliter (EL.U/mL). The cut-off of the assay was 100 EL.U/mL. Data were collected post-Dose 3 at Month 3 and post-Dose 4 at Month 9 for the HIV+/+, HIV+/- and HIV- (3+1) groups,post-Dose 3 at Month 3 and at Month 9 for HIV- (3+0) group, and post-Dose 2 at Month 3 and post-Dose 3 at Month 9 for the HIV- (2+1) Group. The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

At Month 3 and Month 9

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	91	93	94
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD [Month 3] (N=70,91,93,94,97)	4215.1 (3622.3 to 4905)	3397.6 (2917.2 to 3957.1)	3431.8 (2955.1 to 3985.4)	4253.1 (3721 to 4861.4)
Anti-PD [Month 9] (N=66,89,93,93,97)	5443.1 (4705.1 to 6297)	5018.3 (4335.7 to 5808.5)	4576.5 (3938.2 to 5318.3)	930.4 (770 to 1124.2)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD [Month 3] (N=70,91,93,94,97)	2240 (1871 to 2681.9)			
Anti-PD [Month 9] (N=66,89,93,93,97)	3141 (2619 to 3767)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Protein D (PD) by ELISA

End point title	Concentrations of Antibodies Against Protein D (PD) by ELISA

End point description:

Concentrations of antibodies are presented as GMCs expressed as ELISA units per milliliter (EL.U/mL). The cut-off of the assay was 100 EL.U/mL. Data were collected post-Dose 4 at Month 23 for the HIV+/+, HIV+/- and HIV- (3+1) groups and post-Dose 3 at Month 23 for HIV- (3+0) and HIV- (2+1) groups. The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

Up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	86	92	91
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD (N=63,86,92,91,97)	748.3 (581.8 to 962.3)	615.3 (495.8 to 763.4)	503.2 (421 to 601.5)	421.3 (334.2 to 531.1)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD (N=63,86,92,91,97)	323 (255.6 to 408.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Diphtheria Toxoid (DT) and Tetanus Toxoid (TT)

End point title	Concentrations of Antibodies Against Diphtheria Toxoid (DT) and Tetanus Toxoid (TT)

End point description:

Concentrations of antibodies are presented as GMCs expressed as International units per millilitre (IU/mL) The cut-off of the assay is 0.1IU/mL.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

1 month following primary immunization (at Month 3)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	91	93	94
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-DT (N=70,91,93,93,97)	2.42 (1.92 to 3.06)	3.69 (3.19 to 4.26)	3.42 (2.96 to 3.96)	4.2 (3.76 to 4.68)
Anti-TT (N=70,91,93,94,97)	5.03 (4.16 to 6.07)	4.77 (4.03 to 5.63)	4.5 (3.89 to 5.21)	5.03 (4.33 to 5.85)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-DT (N=70,91,93,93,97)	3 (2.58 to 3.49)			
Anti-TT (N=70,91,93,94,97)	4.24 (3.5 to 5.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Diphtheria Toxoid (DT) and Tetanus Toxoid (TT)

End point title	Concentrations of Antibodies Against Diphtheria Toxoid (DT) and Tetanus Toxoid (TT)

End point description:

Concentrations of antibodies are presented as GMCs expressed as International units per millilitre (IU/mL). The cut-off of the assay is 0.1IU/mL.
The According-To-Protocol cohort for immunogenicity at 15-18 months included evaluable subjects from the ATP cohort for Immunogenicity who received the DTPw-HBV/Hib vaccine and for whom assay results were available for antibodies against at least 1 vaccine antigen component after this booster dose vaccine.

End point type	Secondary

End point timeframe:

1 month after the booster dose of DTPw-HBV/Hib vaccine (at Month 15)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	81	91	87
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-DT (N=59,81,91,87,92)	9.57 (7.91 to 11.59)	11.7 (10.28 to 13.32)	10.45 (9.18 to 11.89)	12.67 (10.82 to 14.83)
Anti-TT (N=59,81,91,87,92)	14.44 (12.2 to 17.09)	14.6 (12.58 to 16.95)	16.19 (14.18 to 18.48)	17.69 (15.57 to 20.11)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-DT (N=59,81,91,87,92)	11.96 (10.48 to 13.64)			
Anti-TT (N=59,81,91,87,92)	19.77 (17.74 to 22.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Bordetella Pertussis (BPT) by ELISA

End point title	Concentrations of Antibodies Against Bordetella Pertussis (BPT) by ELISA

End point description:

Concentrations of antibodies are presented as GMCs expressed as ELISA units per millilitre (EL.U/mL). The cut-off of the assay is 15 EL.U/mL.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

1 month following primary immunization (at Month 3)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	91	93	92
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT (N=70,91,93,92,97)	90.86 (74.89 to 110.23)	132.27 (118.6 to 147.51)	143.08 (129.44 to 158.17)	152.23 (137.86 to 168.1)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT (N=70,91,93,92,97)	146.6 (129.19 to 166.34)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Bordetella Pertussis (BPT) by ELISA

End point title	Concentrations of Antibodies Against Bordetella Pertussis (BPT) by ELISA

End point description:

Concentrations of antibodies are presented as GMCs expressed as ELISA units per millilitre (EL.U/mL). The cut-off of the assay is 15 EL.U/mL.
The ATP cohort for immunogenicityat 15-18 months included evaluable subjects from the ATP cohort for Immunogenicity who received the DTPw-HBV/Hib vaccine and for whom assay results were available for antibodies against at least 1 vaccine antigen component after this booster dose vaccine.

End point type	Secondary

End point timeframe:

1 month after the booster dose of DTPw-HBV/Hib vaccine (at Month 15)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	81	90	87
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT (N=59,81,90,87,92)	161.01 (131.88 to 196.58)	227.01 (202.86 to 254.03)	241.77 (218.18 to 267.9)	259.45 (234.7 to 286.81)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT (N=59,81,90,87,92)	267.8 (243.49 to 294.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies against Polyribosyl-ribitol Phosphate (PRP)

End point title	Concentrations of Antibodies against Polyribosyl-ribitol Phosphate (PRP)

End point description:

Concentrations of antibodies are presented as GMCs expressed as microgram per millilitre (µg/mL). The cut-off of the assay is 0.15 µg/mL.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

1 month following primary immunization (at Month 3)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	91	93	93
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti- PRP (N=70,91,93,93,97)	16.71 (11.63 to 24.01)	20.55 (15.78 to 26.78)	20.36 (15.56 to 26.64)	24.22 (18.45 to 31.8)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: µg/mL				

geometric mean (confidence interval 95%)				
Anti- PRP (N=70,91,93,93,97)	21.78 (16.47 to 28.79)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies against Polyribosyl-ribitol Phosphate (PRP)

End point title	Concentrations of Antibodies against Polyribosyl-ribitol Phosphate (PRP)

End point description:

Concentrations of antibodies are presented as GMCs expressed as microgram per millilitre (µg/mL). The cut-off of the assay is 0.15 µg/mL.
The ATP cohort for immunogenicity at 15 -18 months included evaluable subjects from the ATP cohort for Immunogenicity who received the DTPw-HBV/Hib vaccine and for whom assay results were available for antibodies against at least 1 vaccine antigen component after this booster dose vaccine.

End point type	Secondary

End point timeframe:

1 month after the booster vaccination (at Month 15)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	80	91	87
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP (N=59,80,91,87,92)	50.11 (33.29 to 75.43)	71.23 (55.03 to 92.19)	83.46 (64.51 to 107.98)	93.18 (69.67 to 124.64)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP (N=59,80,91,87,92)	129.99 (103.73 to 162.89)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Hepatitis B Surface Antigen (HBs) by ELISA

End point title	Concentrations of Antibodies Against Hepatitis B Surface Antigen (HBs) by ELISA

End point description:

Concentrations of antibodies are presented as GMCs expressed as milli-International units per milliliter (mIU/mL). The cut-off of the assay is 10 mIU/mL. As a decrease in the specificity of the anti-HBs ELISA assay had been observed in some studies for low levels of antibody (10-100 mIU/mL), the table showed results following partial or complete retesting/reanalysis.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

1 month following primary immunization (at Month 3)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	85	88	87
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs (N=63,85,88,87,90)	288.45 (167.12 to 497.86)	478.53 (333.22 to 687.22)	865.5 (654.8 to 1144.1)	904.7 (646 to 1267)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	90			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs (N=63,85,88,87,90)	563.5 (373.8 to 849.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Hepatitis B Surface Antigen (HBs) by ELISA

End point title	Concentrations of Antibodies Against Hepatitis B Surface Antigen (HBs) by ELISA

End point description:

Concentrations of antibodies were presented as GMCs expressed as milli-International units per milliliter (mIU/mL). The cut-off of the assay was 10 mIU/mL. As a decrease in the specificity of the anti-HBs ELISA assay had been observed in some studies for low levels of antibody (10-100 mIU/mL), the table showed results following partial or complete retesting/reanalysis.
The ATP cohort for immunogenicity at 15-18 months included evaluable subjects from the ATP cohort for Immunogenicity who received the DTPw-HBV/Hib vaccine and for whom assay results were available for antibodies against at least 1 vaccine antigen component after this booster dose vaccine.

End point type	Secondary

End point timeframe:

1 month after the booster dose of DTPw-HBV/Hib vaccine (at Month 15)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	78	90	81
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs (N=58,78,90,81,89)	1871 (892.9 to 3920.7)	2507.4 (1500.7 to 4189.4)	3674.4 (2446.9 to 5517.9)	4287.6 (2785.9 to 6598.8)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	89			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs (N=58,78,90,81,89)	3583.4 (2194.8 to 5850.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies against Rotavirus Immunoglobulin A (Rotavirus IgA), by Rotarix Vaccination Status

End point title	Concentrations of Antibodies against Rotavirus Immunoglobulin A (Rotavirus IgA), by Rotarix Vaccination Status

End point description:

Concentrations of antibodies are presented as GMCs expressed as units per millilitre (U/mL). The cut-off of the assay is 20 U/mL. Data were collected for subjects who received 1, 2 doses or no Rotarix dose during the study.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

1 month after the administration of the second vaccine dose (at Month 3)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	59	66	66
Units: U/mL				
geometric mean (confidence interval 95%)				
Anti-rotavirus IgA [2 doses] (N=58,59,66,66,67)	52.6 (33.8 to 81.8)	104.1 (66.3 to 163.5)	146.4 (94.2 to 227.4)	92 (60 to 141)
Anti-rotavirus IgA [1 dose] (N=0,0,1,1,0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Anti-rotavirus IgA [0 dose] (N=11,27,25,24,28)	54.8 (13.1 to 229.2)	54 (21.3 to 136.8)	63.1 (34.8 to 114.5)	47.5 (26.5 to 85.3)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	67			
Units: U/mL				
geometric mean (confidence interval 95%)				
Anti-rotavirus IgA [2 doses] (N=58,59,66,66,67)	74.3 (47.5 to 116.3)			
Anti-rotavirus IgA [1 dose] (N=0,0,1,1,0)	0 (0 to 0)			
Anti-rotavirus IgA [0 dose] (N=11,27,25,24,28)	41.7 (22.3 to 78.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Antibodies Against Measles

End point title	Concentrations of Antibodies Against Measles

End point description:

Concentrations of antibodies are presented as GMCs expressed as milli-International units per milliliter (mIU/mL).The cut-off of the assay is 150 mIU/mL.
The According-To-Protocol cohort for immunogenicity included evaluable subjects for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against at least 1 study vaccine antigen component post dose II or III, as applicable, or after booster vaccination.

End point type	Secondary

End point timeframe:

1 month following administration of the 1st and 2nd vaccine dose (at Months 9 and 15)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	85	91	87
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-Measles [Month 9](N=54,79,82,83,87)	2013.36 (1566.36 to 2587.94)	1917.14 (1468.59 to 2502.68)	1973.84 (1512.9 to 2575.22)	1509.36 (1157.32 to 1968.5)
Anti-Measles [Month 15](N=63,85,91,87,93)	3358.15 (2578.34 to 4373.83)	4189.83 (3451.63 to 5085.91)	3713.51 (3050.3 to 4520.92)	3311.3 (2698.56 to 4063.17)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	93			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-Measles [Month 9](N=54,79,82,83,87)	1719.76 (1360.39 to 2174.08)			
Anti-Measles [Month 15](N=63,85,91,87,93)	3204.79 (2659 to 3862.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-LytC IgA and Anti-PhtD IgA antibodies concentrations in salivary samples

End point title	Anti-LytC IgA and Anti-PhtD IgA antibodies concentrations in salivary samples

End point description:

Salivary antibodies against selected common bacterial protein antigens.
Salivary samples (1.0 mL) were collected by using an Oracol device consisting of a sponge (2 cm3) placed on a stick that was used to brush the teeth and gums to absorb the saliva. Salivary samples was sent to RMPRU (or GSK Biologicals' designated validated laboratory) where the sponge was centrifuged to extract the saliva that was immediately stored at -70°C. The cut-off of the assay was 2.3 U/mL for anti-LytC IgA and 2.2 U/mL for anti PhtD IgA.
The Total Vaccinated cohort included all subjects with at least one vaccine dose administration documented.

End point type	Secondary

End point timeframe:

Up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	95	98	94
Units: U/mL				
geometric mean (confidence interval 95%)				
Anti-LytC [Month0] (N=65,50,46,46,45)	7.71 (5.44 to 10.95)	5.49 (3.81 to 7.91)	6.22 (4.35 to 8.9)	5.98 (4.24 to 8.43)
Anti-LytC [Month3] (N=74,79,95,91,93)	18.3 (13.29 to 25.22)	13.48 (10.46 to 17.37)	13.29 (10.5 to 16.82)	13.81 (10.56 to 18.06)
Anti-LytC [Month8] (N=75,95,98,94,98)	27.23 (18.88 to 39.29)	15.99 (12.29 to 20.79)	24.51 (18.63 to 32.24)	22.64 (16.56 to 30.96)
Anti-LytC [Month9] (N=77,94,98,94,97)	30.96 (20.88 to 45.88)	15.54 (11.72 to 20.61)	24.6 (17.89 to 33.83)	21.06 (15.15 to 29.27)
Anti-LytC [Month11] (N=77,93,98,93,97)	37.01 (24.64 to 55.59)	18.79 (13.94 to 25.32)	43.03 (30.64 to 60.44)	35.65 (26.47 to 48.02)
Anti-LytC [Month14] (N=73,94,98,94,97)	39.45 (28.22 to 55.15)	24.69 (18.48 to 32.97)	39.59 (28.87 to 54.29)	38.87 (29.26 to 51.63)
Anti-LytC [Month15] (N=74,93,97,93,98)	58.11 (38.95 to 86.69)	28.09 (21.12 to 37.36)	42.43 (31.21 to 57.68)	50.45 (38.7 to 65.77)
Anti-LytC [Month23] (N=73,91,97,92,98)	89.32 (63.92 to 124.81)	43.61 (32.16 to 59.14)	68.34 (51.15 to 91.32)	61.4 (48.68 to 77.45)
Anti-PhtD [Month0] (N=65,50,46,46,45)	4.58 (3.36 to 6.25)	3.83 (2.83 to 5.18)	7.85 (5.18 to 11.9)	6.3 (4.39 to 9.04)
Anti-PhtD [Month3] (N=74,79,95,91,93)	5.49 (3.97 to 7.59)	4.92 (3.75 to 6.45)	5.14 (4.07 to 6.49)	5.06 (3.96 to 6.47)
Anti-PhtD [Month8] (N=75,95,98,94,98)	7.77 (5.46 to 11.06)	5.86 (4.51 to 7.62)	9.49 (7.1 to 12.69)	10.01 (7.1 to 14.12)
Anti-PhtD [Month9] (N=77,94,98,94,97)	9.16 (6.37 to 13.17)	7.32 (5.5 to 9.73)	16.47 (11.34 to 23.94)	14.01 (9.77 to 20.11)
Anti-PhtD [Month11] (N=77,93,98,93,97)	9.49 (6.86 to 13.14)	7.92 (5.76 to 10.9)	16.93 (11.58 to 24.75)	15.41 (10.83 to 21.94)
Anti-PhtD [Month14] (N=73,94,98,94,97)	14.06 (9.92 to 19.92)	10.74 (8.01 to 14.4)	19.39 (13.98 to 26.87)	22.04 (16.09 to 30.2)
Anti-PhtD [Month15] (N=74,93,98,93,98)	15.04 (10.08 to 22.46)	11.35 (8.27 to 15.59)	18.06 (13.04 to 25.02)	24.03 (17.55 to 32.92)
Anti-PhtD [Month23] (N=73,91,97,92,98)	41.41 (27.82 to 61.62)	29.17 (20.84 to 40.83)	39.84 (28.47 to 55.75)	35.69 (26.26 to 48.5)

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: U/mL				
geometric mean (confidence interval 95%)				
Anti-LytC [Month0] (N=65,50,46,46,45)	6.67 (4.89 to 9.08)			
Anti-LytC [Month3] (N=74,79,95,91,93)	14.43 (11.32 to 18.39)			
Anti-LytC [Month8] (N=75,95,98,94,98)	21.85 (16.32 to 29.25)			

Anti-LytC [Month9] (N=77,94,98,94,97)	25 (18.66 to 33.5)			
Anti-LytC [Month11] (N=77,93,98,93,97)	38.07 (28.23 to 51.34)			
Anti-LytC [Month14] (N=73,94,98,94,97)	34.75 (26.4 to 45.74)			
Anti-LytC [Month15] (N=74,93,97,93,98)	42.98 (32.28 to 57.22)			
Anti-LytC [Month23] (N=73,91,97,92,98)	59.75 (45.69 to 78.12)			
Anti-PhtD [Month0] (N=65,50,46,46,45)	5.49 (3.73 to 8.08)			
Anti-PhtD [Month3] (N=74,79,95,91,93)	5.1 (4.02 to 6.47)			
Anti-PhtD [Month8] (N=75,95,98,94,98)	8.35 (6.22 to 11.21)			
Anti-PhtD [Month9] (N=77,94,98,94,97)	11.71 (8.45 to 16.23)			
Anti-PhtD [Month11] (N=77,93,98,93,97)	15.7 (11.36 to 21.7)			
Anti-PhtD [Month14] (N=73,94,98,94,97)	14.54 (10.62 to 19.92)			
Anti-PhtD [Month15] (N=74,93,98,93,98)	17.07 (12.08 to 24.12)			
Anti-PhtD [Month23] (N=73,91,97,92,98)	35.92 (26.6 to 48.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of swabs with positive cultures of Haemophilus Influenzae and/or Streptococcus Pneumoniae (Vaccine Serotypes, Cross-reactive or Other Serotypes) and Other Bacterial Pathogens in the Nasopharynx

End point title	Number of swabs with positive cultures of Haemophilus Influenzae and/or Streptococcus Pneumoniae (Vaccine Serotypes, Cross-reactive or Other Serotypes) and Other Bacterial Pathogens in the Nasopharynx

End point description:

Positive cultures of H. influenza* (HI) and S. pneumonia(SP) and other bacterial pathogens such as Moraxella catarrhalis(MC), Group A streptococci and Staphylococcus aureus (SA), identified in the nasopharynx at each swab time point: Month (Mth) 0 (Pre-vaccination time point at 6-12 weeks of age), Mth 3 (18 weeks of age), Mth 8 (9-10 Months of age), Mth 9 (10-11 Months of age), Mth 11 (12-13 Months of age), Mth 14 (15-18 Months of age), Mth 15 (16-19 Months of age) and Mth 23 (24-27 Months of age).
*Data presented only include results from samples confirmed as positive for Hi/Non Typeable Hi after differentiation from H. haemolyticus by PCR assay.
The Total Vaccinated cohort included all subjects with at least one vaccine dose administration documented.

End point type	Secondary

End point timeframe:

Up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	83	101	100	100
Units: Swabs				
Any SP – Mth 0 (N=83,101,100,100,100)	23	24	25	30
Any SP – Mth 3 (N=81,98,98,95,98)	47	62	58	55
Any SP – Mth 8 (N=76,95,98,94,98)	55	61	65	67
Any SP – Mth 9 (N=77,96,98,94,98)	50	64	62	66
Any SP – Mth 11 (N=77,94,98,94,97)	52	61	67	62
Any SP – Mth 14 (N=75,94,98,94,98)	52	64	69	70
Any SP – Mth 15 (N=75,94,98,94,98)	59	68	62	70
Any SP – Mth 23 (N=73,92,97,92,98)	58	59	63	60
Any HI – Mth 0 (N=82,101,99,100,98)	14	12	17	12
Any HI – Mth 3 (N=80,98,98,95,98)	30	34	36	33
Any HI – Mth 8 (N=77,94,97,94,98)	21	41	34	30
Any HI – Mth 9 (N=77,96,97,94,98)	28	47	34	29
Any HI – Mth 11 (N=76,93,96,88,92)	33	44	36	34
Any HI – Mth 14 (N=68,81,81,73,82)	29	39	38	31
Any HI – Mth 15 (N=75,94,98,94,98)	35	54	54	51
Any HI – Mth 23 (N=73,92,97,92,98)	39	45	58	53
Any MC – Mth 0 (N=83,101,100,100,100)	35	39	42	42
Any MC – Mth 3 (N=81,98,98,95,98)	63	88	88	87
Any MC – Mth 8 (N=77,95,98,94,98)	56	83	84	79
Any MC – Mth 9 (N=77,96,98,94,98)	62	79	75	81
Any MC – Mth 11 (N=77,94,98,94,97)	69	80	73	73
Any MC – Mth 14 (N=75,94,98,94,98)	65	81	84	90
Any MC – Mth 15 (N=75,94,98,94,98)	60	82	83	87
Any MC – Mth 23 (N=73,92,97,92,98)	59	73	78	71
Any SA – Mth 0 (N=83,101,100,100,100)	37	48	56	57
Any SA – Mth 3 (N=81,98,98,95,98)	41	37	37	40
Any SA – Mth 8 (N=77,95,98,94,98)	16	18	13	19
Any SA – Mth 9 (N=77,96,98,94,98)	19	26	18	16
Any SA – Mth 11 (N=77,94,98,94,97)	9	18	13	13
Any SA – Mth 14 (N=75,94,98,94,98)	11	15	9	13
Any SA – Mth 15 (N=75,94,98,94,98)	12	11	20	13
Any SA – Mth 23 (N=73,92,97,92,98)	8	16	10	13

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: Swabs				
Any SP – Mth 0 (N=83,101,100,100,100)	17			
Any SP – Mth 3 (N=81,98,98,95,98)	64			
Any SP – Mth 8 (N=76,95,98,94,98)	67			
Any SP – Mth 9 (N=77,96,98,94,98)	70			

Any SP – Mth 11 (N=77,94,98,94,97)	70			
Any SP – Mth 14 (N=75,94,98,94,98)	70			
Any SP – Mth 15 (N=75,94,98,94,98)	68			
Any SP – Mth 23 (N=73,92,97,92,98)	66			
Any HI – Mth 0 (N=82,101,99,100,98)	12			
Any HI – Mth 3 (N=80,98,98,95,98)	37			
Any HI – Mth 8 (N=77,94,97,94,98)	38			
Any HI – Mth 9 (N=77,96,97,94,98)	32			
Any HI – Mth 11 (N=76,93,96,88,92)	40			
Any HI – Mth 14 (N=68,81,81,73,82)	27			
Any HI – Mth 15 (N=75,94,98,94,98)	55			
Any HI – Mth 23 (N=73,92,97,92,98)	62			
Any MC – Mth 0 (N=83,101,100,100,100)	44			
Any MC – Mth 3 (N=81,98,98,95,98)	90			
Any MC – Mth 8 (N=77,95,98,94,98)	82			
Any MC – Mth 9 (N=77,96,98,94,98)	72			
Any MC – Mth 11 (N=77,94,98,94,97)	83			
Any MC – Mth 14 (N=75,94,98,94,98)	84			
Any MC – Mth 15 (N=75,94,98,94,98)	86			
Any MC – Mth 23 (N=73,92,97,92,98)	79			
Any SA – Mth 0 (N=83,101,100,100,100)	55			
Any SA – Mth 3 (N=81,98,98,95,98)	32			
Any SA – Mth 8 (N=77,95,98,94,98)	24			
Any SA – Mth 9 (N=77,96,98,94,98)	17			
Any SA – Mth 11 (N=77,94,98,94,97)	19			
Any SA – Mth 14 (N=75,94,98,94,98)	13			
Any SA – Mth 15 (N=75,94,98,94,98)	18			
Any SA – Mth 23 (N=73,92,97,92,98)	18			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with acquisition of new Streptococcus pneumoniae and Haemophilus Influenzae strains identified in nasopharyngeal swabs

End point title	Number of subjects with acquisition of new Streptococcus pneumoniae and Haemophilus Influenzae strains identified in nasopharyngeal swabs

End point description:

Acquisition of new H. influenza* (HI) and S. pneumonia(SP) strains, identified in the nasopharynx at each swab time point: Month (Mth) 3 (18 weeks of age), Mth 8 (9-10 Months of age), Mth 9 (10-11 Months of age), Mth 11 (12-13 Months of age), Mth 14 (15-18 Months of age), Mth 15 (16-19 Months of age) and Mth 23 (24-27 Months of age).
*Data presented only include results from samples confirmed as positive for Hi/Non Typeable Hi after differentiation from H. haemolyticus by PCR assay.
The Total Vaccinated cohort included all subjects with at least one vaccine dose administration documented.

End point type	Secondary

End point timeframe:

Up to study end at Month 23 (24-27 months of age)

End point values	HIV+/+ Group	HIV+/- Group	HIV-(3+1) Group	HIV- (3+0) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	98	98	95
Units: Subjects				
Any SP – Mth 3 (N=81,98,98,95,98)	35	47	46	41
Any SP – Mth 8 (N=77,95,98,94,98)	59	68	70	67
Any SP – Mth 9 (N=77,95,98,94,98)	64	76	77	78
Any SP – Mth 11 (N=77,93,98,94,97)	69	79	84	84
Any SP – Mth 14 (N=75,92,98,94,97)	68	82	90	90
Any SP – Mth 15 (N=75,92,98,94,97)	72	86	90	92
Any SP – Mth 23 (N=73,90,97,92,97)	72	87	95	90
Any HI – Mth 3 (N=80,98,97,95,96)	26	25	27	29
Any HI – Mth 8 (N=76,94,96,94,96)	34	49	48	42
Any HI – Mth 9 (N=76,94,95,94,96)	45	63	52	52
Any HI – Mth 11 (N=75,91,94,88,92)	55	67	60	57
Any HI – Mth 14 (N=67,78,78,70,78)	56	60	58	54
Any HI – Mth 15 (N=67,78,78,70,78)	59	67	64	58
Any HI – Mth 23 (N=65,76,77,69,78)	60	70	71	59

End point values	HIV-(2+1) Group			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: Subjects				
Any SP – Mth 3 (N=81,98,98,95,98)	56			
Any SP – Mth 8 (N=77,95,98,94,98)	76			
Any SP – Mth 9 (N=77,95,98,94,98)	82			
Any SP – Mth 11 (N=77,93,98,94,97)	90			
Any SP – Mth 14 (N=75,92,98,94,97)	93			
Any SP – Mth 15 (N=75,92,98,94,97)	94			
Any SP – Mth 23 (N=73,90,97,92,97)	96			
Any HI – Mth 3 (N=80,98,97,95,96)	30			
Any HI – Mth 8 (N=76,94,96,94,96)	45			
Any HI – Mth 9 (N=76,94,95,94,96)	57			
Any HI – Mth 11 (N=75,91,94,88,92)	65			
Any HI – Mth 14 (N=67,78,78,70,78)	59			
Any HI – Mth 15 (N=67,78,78,70,78)	65			
Any HI – Mth 23 (N=65,76,77,69,78)	71			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

SAEs: from Month 0 up to Month 23. Unsolicited AEs: within the 31-day post-primary and post Synflorix booster vaccination period. Solicited AEs: During the 4-day period following the primary and the Synflorix booster vaccination.

Adverse event reporting additional description:

The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	HIV+/+ Group

Reporting group description:

Infants born from a HIV positive mother and confirmed as HIV infected. Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered intramuscularly in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV+/- Group

Reporting group description:

Infants born from a HIV positive mother and confirmed as HIV exposed uninfected. Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix- HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV- (3+1) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 3 primary doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix- HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV- (3+0) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected.Subjects received 3 primary doses of Synflorix vaccine (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the

Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Reporting group title	HIV- (2+1) Group

Reporting group description:

Infants born from a HIV negative mother and confirmed as HIV unexposed uninfected. Subjects received 2 primary doses (at 6 & 14 weeks of age at study Months 0 and 2) and 1 booster dose of Synflorix vaccine (at 9 months of age, at study Month 8). Subjects in the group also received 3 primary vaccine doses (at 6, 10 & 14 weeks of age, at study Months 0, 1 and 2) and 1 booster vaccine dose (at 15-18 months of age, at study Month 14) of Tritanrix-HepB/Hib, 2 vaccine doses of Rotarix (at 10 & 14 weeks of age, at study Months 1 and 2), and 2 doses of measles vaccine (9-10 months of age & 15-18 months of age, at study Months 8 and 14). Measles vaccine was not considered as a study vaccine. The Synflorix vaccine was administered IM in the right thigh, the Tritanrix-HepB/Hib vaccine was administered IM in the left anterolateral thigh during the primary vaccination and in the left anterolateral thigh or left deltoid region during booster vaccination. Rotarix was given orally.

Serious adverse events	HIV+/+ Group	HIV+/- Group	HIV- (3+1) Group
Total subjects affected by serious adverse events			
subjects affected / exposed	31 / 83 (37.35%)	25 / 101 (24.75%)	20 / 100 (20.00%)
number of deaths (all causes)	5	4	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Herbal toxicity			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Near drowning			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Thermal burn			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Burns second degree			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Electric shock			

subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Congenital, familial and genetic disorders			
Cerebral palsy			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Trisomy 21			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Ventricular septal defect			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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			
Convulsion			
subjects affected / exposed	1 / 83 (1.20%)	1 / 101 (0.99%)	0 / 100 (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
Febrile convulsion			
subjects affected / exposed	1 / 83 (1.20%)	1 / 101 (0.99%)	3 / 100 (3.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Encephalopathy			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 83 (1.20%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Sudden death			
subjects affected / exposed	2 / 83 (2.41%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Sudden infant death syndrome			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vomiting			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			

subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Hepatobiliary disorders			
Hepatitis neonatal			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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			
Atelectasis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Bronchospasm			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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 aspiration			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Asthma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	1 / 83 (1.20%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infections and infestations			
AIDS dementia complex			

subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Bronchitis			
subjects affected / exposed	1 / 83 (1.20%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	13 / 83 (15.66%)	5 / 101 (4.95%)	6 / 100 (6.00%)
occurrences causally related to treatment / all	0 / 13	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Croup infectious			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Cytomegalovirus infection			
subjects affected / exposed	2 / 83 (2.41%)	0 / 101 (0.00%)	0 / 100 (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
Gastroenteritis			
subjects affected / exposed	8 / 83 (9.64%)	8 / 101 (7.92%)	5 / 100 (5.00%)
occurrences causally related to treatment / all	1 / 8	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Measles			

subjects affected / exposed	1 / 83 (1.20%)	2 / 101 (1.98%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Meningitis meningococcal			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Meningitis tuberculous			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Pneumococcal sepsis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Pneumocystis jiroveci pneumonia			
subjects affected / exposed	4 / 83 (4.82%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 83 (1.20%)	1 / 101 (0.99%)	3 / 100 (3.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Pulmonary tuberculosis			

subjects affected / exposed	11 / 83 (13.25%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 11	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Tuberculosis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Upper respiratory tract infection			
subjects affected / exposed	1 / 83 (1.20%)	3 / 101 (2.97%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 83 (1.20%)	3 / 101 (2.97%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 83 (1.20%)	3 / 101 (2.97%)	4 / 100 (4.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Abscess limb			

subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Arthritis bacterial			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site abscess			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Lobar pneumonia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Oral herpes			
subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Otitis media			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Subacute endocarditis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Tonsillitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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			
Kwashiorkor			
subjects affected / exposed	2 / 83 (2.41%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Marasmus			
subjects affected / exposed	1 / 83 (1.20%)	0 / 101 (0.00%)	0 / 100 (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
Hypokalaemia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 101 (0.99%)	0 / 100 (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

Serious adverse events	HIV- (3+0) Group	HIV- (2+1) Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 100 (15.00%)	20 / 100 (20.00%)	
number of deaths (all causes)	3	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Herbal toxicity			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Near drowning			

subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns second degree			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electric shock			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Cerebral palsy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trisomy 21			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Convulsion			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Febrile convulsion			
subjects affected / exposed	1 / 100 (1.00%)	2 / 100 (2.00%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Sudden infant death syndrome			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatitis neonatal			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			

subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
AIDS dementia complex			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	1 / 100 (1.00%)	8 / 100 (8.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Croup infectious			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	4 / 100 (4.00%)	4 / 100 (4.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1N1 influenza			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Measles			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis meningococcal			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis tuberculous			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jiroveci pneumonia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			

subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site abscess			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobar pneumonia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral herpes			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			

subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subacute endocarditis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Kwashiorkor			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Marasmus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	HIV+/+ Group	HIV+/- Group	HIV- (3+1) Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	83 / 83 (100.00%)	100 / 101 (99.01%)	98 / 100 (98.00%)
General disorders and administration site conditions			
Diarrhoea (unsolicited post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[1]	13 / 83 (15.66%)	16 / 101 (15.84%)	18 / 98 (18.37%)
occurrences (all)	13	16	18
Drowsiness (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[2]	49 / 83 (59.04%)	62 / 101 (61.39%)	70 / 98 (71.43%)
occurrences (all)	49	62	70
Drowsiness (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[3]	17 / 74 (22.97%)	28 / 95 (29.47%)	34 / 96 (35.42%)
occurrences (all)	17	28	34
Fever (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[4]	38 / 83 (45.78%)	36 / 101 (35.64%)	41 / 98 (41.84%)
occurrences (all)	38	36	41
Fever (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	9 / 74 (12.16%)	11 / 95 (11.58%)	7 / 96 (7.29%)
occurrences (all)	9	11	7
Irritability (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[6]	63 / 83 (75.90%)	84 / 101 (83.17%)	89 / 98 (90.82%)
occurrences (all)	63	84	89
Irritability (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[7]	25 / 74 (33.78%)	35 / 95 (36.84%)	31 / 96 (32.29%)
occurrences (all)	25	35	31
Decreased appetite (post-primary)			
alternative assessment type: Systematic			

subjects affected / exposed[8]	36 / 83 (43.37%)	53 / 101 (52.48%)	56 / 98 (57.14%)
occurrences (all)	36	53	56
Decreased appetite (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[9]	17 / 74 (22.97%)	23 / 95 (24.21%)	29 / 96 (30.21%)
occurrences (all)	17	23	29
Pain (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[10]	73 / 83 (87.95%)	93 / 101 (92.08%)	92 / 98 (93.88%)
occurrences (all)	73	93	92
Pain (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[11]	40 / 74 (54.05%)	58 / 95 (61.05%)	62 / 96 (64.58%)
occurrences (all)	40	58	62
Redness (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[12]	62 / 83 (74.70%)	80 / 101 (79.21%)	83 / 98 (84.69%)
occurrences (all)	62	80	83
Redness (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[13]	25 / 74 (33.78%)	31 / 95 (32.63%)	39 / 96 (40.63%)
occurrences (all)	25	31	39
Swelling (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[14]	67 / 83 (80.72%)	83 / 101 (82.18%)	84 / 98 (85.71%)
occurrences (all)	67	83	84
Swelling (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[15]	28 / 74 (37.84%)	39 / 95 (41.05%)	38 / 96 (39.58%)
occurrences (all)	28	39	38
Vomiting (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[16]	17 / 83 (20.48%)	19 / 101 (18.81%)	15 / 98 (15.31%)
occurrences (all)	17	19	15

Pyrexia (unsolicited post-primary)			
subjects affected / exposed	5 / 83 (6.02%)	8 / 101 (7.92%)	5 / 100 (5.00%)
occurrences (all)	5	8	5
Eye disorders			
Eye discharge (unsolicited post-primary)			
subjects affected / exposed	4 / 83 (4.82%)	6 / 101 (5.94%)	6 / 100 (6.00%)
occurrences (all)	4	6	6
Gastrointestinal disorders			
Diarrhoea (unsolicited post-primary)			
subjects affected / exposed	13 / 83 (15.66%)	16 / 101 (15.84%)	18 / 100 (18.00%)
occurrences (all)	13	16	18
Diarrhoea (post-booster)			
subjects affected / exposed[17]	5 / 76 (6.58%)	10 / 96 (10.42%)	10 / 98 (10.20%)
occurrences (all)	5	10	10
Vomiting (unsolicited post-primary)			
subjects affected / exposed	18 / 83 (21.69%)	16 / 101 (15.84%)	11 / 100 (11.00%)
occurrences (all)	18	16	11
Vomiting (unsolicited post-booster)			
subjects affected / exposed[18]	1 / 76 (1.32%)	8 / 96 (8.33%)	7 / 98 (7.14%)
occurrences (all)	1	8	7
Abdominal pain upper (unsolicited post-primary)			
subjects affected / exposed	4 / 83 (4.82%)	1 / 101 (0.99%)	4 / 100 (4.00%)
occurrences (all)	4	1	4
Constipation (unsolicited post-primary)			
subjects affected / exposed	0 / 83 (0.00%)	3 / 101 (2.97%)	3 / 100 (3.00%)
occurrences (all)	0	3	3
Respiratory, thoracic and mediastinal disorders			
Cough (unsolicited post-primary)			
subjects affected / exposed	35 / 83 (42.17%)	73 / 101 (72.28%)	67 / 100 (67.00%)
occurrences (all)	35	73	67
Cough (unsolicited post-booster)			
subjects affected / exposed[19]	17 / 76 (22.37%)	23 / 96 (23.96%)	24 / 98 (24.49%)
occurrences (all)	17	23	24
Nasal Obstruction (unsolicited post-primary)			

subjects affected / exposed	29 / 83 (34.94%)	40 / 101 (39.60%)	50 / 100 (50.00%)
occurrences (all)	29	40	50
Nasal Obstruction (unsolicited post-booster)			
subjects affected / exposed[20]	7 / 76 (9.21%)	4 / 96 (4.17%)	6 / 98 (6.12%)
occurrences (all)	7	4	6
Rhinorrhoea (unsolicited post-booster)			
subjects affected / exposed[21]	1 / 76 (1.32%)	5 / 96 (5.21%)	7 / 98 (7.14%)
occurrences (all)	1	5	7
Rhinorrhoea (unsolicited post-primary)			
subjects affected / exposed	3 / 83 (3.61%)	9 / 101 (8.91%)	10 / 100 (10.00%)
occurrences (all)	3	9	10
Sneezing (unsolicited post-primary)			
subjects affected / exposed	0 / 83 (0.00%)	9 / 101 (8.91%)	11 / 100 (11.00%)
occurrences (all)	0	9	11
Skin and subcutaneous tissue disorders			
Eczema (unsolicited post-booster)			
subjects affected / exposed	9 / 83 (10.84%)	12 / 101 (11.88%)	11 / 100 (11.00%)
occurrences (all)	9	12	11
Rash (unsolicited post-primary)			
subjects affected / exposed	26 / 83 (31.33%)	25 / 101 (24.75%)	16 / 100 (16.00%)
occurrences (all)	26	25	16
Rash (unsolicited post-booster)			
subjects affected / exposed[22]	4 / 76 (5.26%)	4 / 96 (4.17%)	3 / 98 (3.06%)
occurrences (all)	4	4	3
Dermatitis diaper (unsolicited post-primary)			
subjects affected / exposed	12 / 83 (14.46%)	8 / 101 (7.92%)	11 / 100 (11.00%)
occurrences (all)	12	8	11
Infections and infestations			
Upper respiratory tract infection (unsolicited post-primary)			
subjects affected / exposed	4 / 83 (4.82%)	13 / 101 (12.87%)	13 / 100 (13.00%)
occurrences (all)	4	13	13
Upper respiratory tract infection (unsolicited post-booster)			

subjects affected / exposed[23]	2 / 76 (2.63%)	5 / 96 (5.21%)	6 / 98 (6.12%)
occurrences (all)	2	5	6
Bronchiolitis (unsolicited post-primary)			
subjects affected / exposed	1 / 83 (1.20%)	6 / 101 (5.94%)	3 / 100 (3.00%)
occurrences (all)	1	6	3
Bronchopneumonia (unsolicited post-primary)			
subjects affected / exposed	5 / 83 (6.02%)	3 / 101 (2.97%)	3 / 100 (3.00%)
occurrences (all)	5	3	3
Oral candidiasis (unsolicited post-primary)			
subjects affected / exposed	9 / 83 (10.84%)	4 / 101 (3.96%)	6 / 100 (6.00%)
occurrences (all)	9	4	6
Metabolism and nutrition disorders			
Decreased appetite (unsolicited post-booster)			
subjects affected / exposed[24]	4 / 76 (5.26%)	6 / 96 (6.25%)	4 / 98 (4.08%)
occurrences (all)	4	6	4
Decreased appetite (unsolicited post-primary)			
subjects affected / exposed	6 / 83 (7.23%)	9 / 101 (8.91%)	1 / 100 (1.00%)
occurrences (all)	6	9	1

Non-serious adverse events	HIV- (3+0) Group	HIV- (2+1) Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	98 / 100 (98.00%)	98 / 100 (98.00%)	
General disorders and administration site conditions			
Diarrhoea (unsolicited post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[1]	10 / 98 (10.20%)	5 / 98 (5.10%)	
occurrences (all)	10	5	
Drowsiness (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[2]	70 / 98 (71.43%)	68 / 98 (69.39%)	
occurrences (all)	70	68	
Drowsiness (post-booster)			
alternative assessment type: Systematic			

subjects affected / exposed[3]	0 / 100 (0.00%)	33 / 96 (34.38%)	
occurrences (all)	0	33	
Fever (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[4]	28 / 98 (28.57%)	28 / 98 (28.57%)	
occurrences (all)	28	28	
Fever (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 100 (0.00%)	11 / 96 (11.46%)	
occurrences (all)	0	11	
Irritability (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[6]	89 / 98 (90.82%)	91 / 98 (92.86%)	
occurrences (all)	89	91	
Irritability (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 100 (0.00%)	43 / 96 (44.79%)	
occurrences (all)	0	43	
Decreased appetite (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[8]	57 / 98 (58.16%)	62 / 98 (63.27%)	
occurrences (all)	57	62	
Decreased appetite (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 100 (0.00%)	37 / 96 (38.54%)	
occurrences (all)	0	37	
Pain (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[10]	95 / 98 (96.94%)	97 / 98 (98.98%)	
occurrences (all)	95	97	
Pain (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 100 (0.00%)	60 / 96 (62.50%)	
occurrences (all)	0	60	

Redness (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[12]	83 / 98 (84.69%)	84 / 98 (85.71%)	
occurrences (all)	83	84	
Redness (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 100 (0.00%)	45 / 96 (46.88%)	
occurrences (all)	0	45	
Swelling (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[14]	91 / 98 (92.86%)	84 / 98 (85.71%)	
occurrences (all)	91	84	
Swelling (post-booster)			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 100 (0.00%)	53 / 96 (55.21%)	
occurrences (all)	0	53	
Vomiting (post-primary)			
alternative assessment type: Systematic			
subjects affected / exposed[16]	18 / 98 (18.37%)	23 / 98 (23.47%)	
occurrences (all)	18	23	
Pyrexia (unsolicited post-primary)			
subjects affected / exposed	9 / 100 (9.00%)	9 / 100 (9.00%)	
occurrences (all)	9	9	
Eye disorders			
Eye discharge (unsolicited post-primary)			
subjects affected / exposed	4 / 100 (4.00%)	3 / 100 (3.00%)	
occurrences (all)	4	3	
Gastrointestinal disorders			
Diarrhoea (unsolicited post-primary)			
subjects affected / exposed	13 / 100 (13.00%)	11 / 100 (11.00%)	
occurrences (all)	13	11	
Diarrhoea (post-booster)			
subjects affected / exposed[17]	0 / 100 (0.00%)	8 / 98 (8.16%)	
occurrences (all)	0	8	
Vomiting (unsolicited post-primary)			

subjects affected / exposed	15 / 100 (15.00%)	12 / 100 (12.00%)	
occurrences (all)	15	12	
Vomiting (unsolicited post-booster)			
subjects affected / exposed[18]	0 / 100 (0.00%)	5 / 98 (5.10%)	
occurrences (all)	0	5	
Abdominal pain upper (unsolicited post-primary)			
subjects affected / exposed	3 / 100 (3.00%)	9 / 100 (9.00%)	
occurrences (all)	3	9	
Constipation (unsolicited post-primary)			
subjects affected / exposed	5 / 100 (5.00%)	6 / 100 (6.00%)	
occurrences (all)	5	6	
Respiratory, thoracic and mediastinal disorders			
Cough (unsolicited post-primary)			
subjects affected / exposed	58 / 100 (58.00%)	66 / 100 (66.00%)	
occurrences (all)	58	66	
Cough (unsolicited post-booster)			
subjects affected / exposed[19]	0 / 100 (0.00%)	13 / 98 (13.27%)	
occurrences (all)	0	13	
Nasal Obstruction (unsolicited post-primary)			
subjects affected / exposed	49 / 100 (49.00%)	51 / 100 (51.00%)	
occurrences (all)	49	51	
Nasal Obstruction (unsolicited post-booster)			
subjects affected / exposed[20]	0 / 100 (0.00%)	6 / 98 (6.12%)	
occurrences (all)	0	6	
Rhinorrhoea (unsolicited post-booster)			
subjects affected / exposed[21]	0 / 100 (0.00%)	5 / 98 (5.10%)	
occurrences (all)	0	5	
Rhinorrhoea (unsolicited post-primary)			
subjects affected / exposed	9 / 100 (9.00%)	10 / 100 (10.00%)	
occurrences (all)	9	10	
Sneezing (unsolicited post-primary)			

subjects affected / exposed	6 / 100 (6.00%)	9 / 100 (9.00%)	
occurrences (all)	6	9	
Skin and subcutaneous tissue disorders			
Eczema (unsolicited post-booster)			
subjects affected / exposed	12 / 100 (12.00%)	14 / 100 (14.00%)	
occurrences (all)	12	14	
Rash (unsolicited post-primary)			
subjects affected / exposed	28 / 100 (28.00%)	21 / 100 (21.00%)	
occurrences (all)	28	21	
Rash (unsolicited post-booster)			
subjects affected / exposed[22]	0 / 100 (0.00%)	5 / 98 (5.10%)	
occurrences (all)	0	5	
Dermatitis diaper (unsolicited post-primary)			
subjects affected / exposed	8 / 100 (8.00%)	4 / 100 (4.00%)	
occurrences (all)	8	4	
Infections and infestations			
Upper respiratory tract infection (unsolicited post-primary)			
subjects affected / exposed	11 / 100 (11.00%)	12 / 100 (12.00%)	
occurrences (all)	11	12	
Upper respiratory tract infection (unsolicited post-booster)			
subjects affected / exposed[23]	0 / 100 (0.00%)	5 / 98 (5.10%)	
occurrences (all)	0	5	
Bronchiolitis (unsolicited post-primary)			
subjects affected / exposed	8 / 100 (8.00%)	2 / 100 (2.00%)	
occurrences (all)	8	2	
Bronchopneumonia (unsolicited post-primary)			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	
occurrences (all)	0	2	
Oral candidiasis (unsolicited post-primary)			
subjects affected / exposed	3 / 100 (3.00%)	3 / 100 (3.00%)	
occurrences (all)	3	3	
Metabolism and nutrition disorders			

Decreased appetite (unsolicited post-booster)			
subjects affected / exposed[24]	0 / 100 (0.00%)	4 / 98 (4.08%)	
occurrences (all)	0	4	
Decreased appetite (unsolicited post-primary)			
subjects affected / exposed	3 / 100 (3.00%)	3 / 100 (3.00%)	
occurrences (all)	3	3	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Assessment for this event was performed solely on subjects with their symptom sheets completed.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 December 2008	• Introduction of Prevenar in the national recommended vaccination program of South Africa as from April 2009. • Decision to consider rotavirus vaccine as study vaccine due to its anticipated introduction into the national vaccination program during 2009. • Addition of a rationale for including HIV exposed uninfected children in the study.
29 June 2009	• Decision to test immunogenicity of the oral poliovirus vaccine (OPV) on request of local authorities. • Permission for inclusion of HIV infected infants with weight for age < 3rd percentile at Visit 1, using standard growth charts, at the discretion of the investigator.
24 February 2010	As a slow enrolment rate of HIV+/+ subjects was observed, it was decided to extend the recruitment time by approximately 6 months in Amendment 3 in order to increase the chance to reach target enrolment in the HIV+/+ study group.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study aimed to enrol 100 HIV +/+ subjects but succeed to enrol 83 mainly due to decrease of vertical HIV transmission in South Africa. Some subjects HIV + at screening, tested negative at subsequent HIV testing, were reallocated in HIV+/-Group.

Notes: