Clinical trial results:
A phase III, double blind (observer-blind), randomized, controlled multi-center study to evaluate, in infants and children, the efficacy of the RTS, S/AS01E candidate vaccine against malaria disease caused by P. falciparum infection, across diverse malaria transmission settings in Africa.

Summary

EudraCT number	2012-005716-26
Trial protocol	Outside EU/EEA
Global end of trial date	31 January 2014

Results information

Result version number	v3 (current)
This version publication date	15 February 2023
First version publication date	01 August 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	110021

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00866619
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 July 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

-To evaluate the protective efficacy of RTS,S/AS01E against clinical malaria disease caused by Plasmodium falciparum in African children aged at first dose between 6-12 weeks and received the vaccine in co-administration with DTPwHepB/Hib antigens (Tritanrix HepB/Hib) and OPV. Duration of follow-up was for a minimum of 12 months and a maximum of 18 months after completion of the primary course (Primary Analysis).
-To evaluate the protective efficacy of RTS,S/AS01E against clinical malaria disease caused by Plasmodium falciparum in African children aged at first dose between 5-17 months. Duration of follow-up was for a minimum of 12 months and a maximum of 18 months after completion of the primary course (Primary Analysis).

Protection of trial subjects:

The vaccinees were observed closely for at least 30 minutes following the administration of all vaccines used in the study, with appropriate medical treatment readily available in case of an anaphylactic reaction. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines/products. Children and infants who received an incomplete primary vaccination schedule (not the 3 doses within the expected timings) did not receive the booster dose of RTS,S/AS01E or control vaccine.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 March 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Tanzania, United Republic of: 3210
Country: Number of subjects enrolled	Ghana: 2621
Country: Number of subjects enrolled	Mozambique: 1637
Country: Number of subjects enrolled	Malawi: 1626
Country: Number of subjects enrolled	Gabon: 930
Country: Number of subjects enrolled	Kenya: 4154
Country: Number of subjects enrolled	Burkina Faso: 1281
Worldwide total number of subjects	15459
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)	15459
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 study included 3 phases, a primary (PRI) phase (Months 0-3) and a booster (BST) phase at Month 20, each followed by a related PRI/BST efficacy, immunogenicity and safety (EIS) follow-up (FU) phase, and an EIS extension, from Month 32 to the median of Month 48 or Month 38 time point.

Pre-assignment

Screening details:

Screening included the following: check for inclusion/exclusion criteria, vaccination contraindications/precautions, subjects' medical history and signing informed consent forms.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK257049 [5-17M] Group

Arm description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by either a booster dose of the same GSK257049 vaccine or a dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Arm type	Experimental
Investigational medicinal product name	Malaria Vaccine 257049
Investigational medicinal product code	GSK257049
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid

Investigational medicinal product name	Meningococcal C Conjugate Vaccine
Investigational medicinal product code	
Other name	Menjugate
Pharmaceutical forms	Powder and suspension for suspension for injection, Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid.

Arm title	GSK257049 [6-12W] Group

Arm description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by either a booster dose of the GSK257049 and Polio Sabin™ vaccines or a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Arm type	Experimental

Investigational medicinal product name	257049
Investigational medicinal product code	GSK257049
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid

Investigational medicinal product name	Polio Sabin Oral Polio Vaccine (GSK)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

3 doses administered orally

Investigational medicinal product name	TritanrixHepB/Hib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection, Powder and solvent for suspension for injection, Suspension for injection, Powder and solution for solution for injection, Oral suspension
Routes of administration	Intramuscular use, Oral use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid

Investigational medicinal product name	Meningococcal C Conjugate Vaccine
Investigational medicinal product code	
Other name	Menjugate
Pharmaceutical forms	Powder and suspension for suspension for injection, Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid.

Arm title	VeroRab Comparator [5-17M] Group

Arm description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the VeroRab® vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Arm type	Active comparator
Investigational medicinal product name	Meningococcal C Conjugate Vaccine
Investigational medicinal product code	
Other name	Menjugate
Pharmaceutical forms	Powder and suspension for suspension for injection, Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid

Investigational medicinal product name	Cell-culture rabies vaccine
Investigational medicinal product code	
Other name	VeroRab
Pharmaceutical forms	Powder and suspension for suspension for injection, Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid

Arm title	Menjugate Comparator [6-12W] Group

Arm description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of Menjugate® vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 12. All vaccines have been administered intramuscularly in the left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Arm type	Experimental
Investigational medicinal product name	Meningococcal C Conjugate Vaccine
Investigational medicinal product code	
Other name	Menjugate
Pharmaceutical forms	Powder and suspension for suspension for injection, Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid

Investigational medicinal product name	TritanrixHepB/Hib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection, Powder and solvent for suspension for injection, Suspension for injection, Powder and solution for solution for injection, Oral suspension
Routes of administration	Intramuscular use, Oral use

Dosage and administration details:

3 doses administered intramuscularly into the left deltoid

Investigational medicinal product name	Polio Sabin Oral Polio Vaccine (GSK)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection, Suspension for injection, Oral suspension
Routes of administration	Oral use

Dosage and administration details:

3 doses administered orally

Number of subjects in period 1	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group
Started	5948	4358	2974
Completed	4102	3088	2085
Not completed	1846	1270	889
Consent withdrawn by subject	587	295	272
Adverse event, non-fatal	112	106	47
Lost to follow-up	1145	830	568

Protocol deviation	2	39	2

Number of subjects in period 1	Menjugate Comparator [6-12W] Group
Started	2179
Completed	1549
Not completed	630
Consent withdrawn by subject	144
Adverse event, non-fatal	44
Lost to follow-up	425
Protocol deviation	17

Baseline characteristics

Reporting groups	
Reporting group title	GSK257049 [5-17M] Group
Reporting group description:	
Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by either a booster dose of the same GSK257049 vaccine or a dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.	
Reporting group title	GSK257049 [6-12W] Group
Reporting group description:	
Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by either a booster dose of the GSK257049 and Polio Sabin™ vaccines or a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.	
Reporting group title	VeroRab Comparator [5-17M] Group
Reporting group description:	
Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the VeroRab® vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.	
Reporting group title	Menjugate Comparator [6-12W] Group
Reporting group description:	
Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of Menjugate® vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 12. All vaccines have been administered intramuscularly in the left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.	

Reporting group values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group
Number of subjects	5948	4358	2974
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)	5948	4358	2974
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: Months			
arithmetic mean	10.6	1.2	10.6
standard deviation	± 3.8	± 0.4	± 3.7

Sex: Female, Male Units: Participants			
Female	2967	2124	1503
Male	2981	2234	1471

Reporting group values	Menjugate Comparator [6-12W] Group	Total	
Number of subjects	2179	15459	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	2179	15459	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: Months			
arithmetic mean	1.2		
standard deviation	± 0.4	-	
Sex: Female, Male Units: Participants			
Female	1100	7694	
Male	1079	7765	

Subject analysis sets

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine,

which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 Group
Subject analysis set type	Per protocol

Subject analysis set description:

For the purpose of the analysis, GSK257049 [5-17M] and GSK257049 [6-12W] groups have been pooled into a single group.

Subject analysis set title	Comparator Group
Subject analysis set type	Per protocol

Subject analysis set description:

For the purpose of the analysis, VeroRab Comparator [5-17M] and Menjugate Comparator [6-12W] groups have been pooled into a single group.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and

Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the

GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose

primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 [5-17M] Group and GSK257049 [6-12W] Group.

Subject analysis set title	GSK257049 -GSK257049 Group

Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 -GSK257049 [5-17M] Group and GSK257049 -GSK257049 [6-12W] Group.

Subject analysis set title	GSK257049 - Menjugate Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 - Menjugate [5-17M] Group and GSK257049 - Menjugate [6-12W] Group.

Subject analysis set title	Comparator Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled Group between VeroRab Comparator [5-17M] Group and Menjugate Comparator [6-12W] Group.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 -GSK257049 Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 -GSK257049 [5-17M] Group and GSK257049 -GSK257049 [6-12W] Group.

Subject analysis set title	GSK257049 - Menjugate Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 - Menjugate [5-17M] Group and GSK257049 - Menjugate [6-12W] Group.

Subject analysis set title	Comparator Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled Group between VeroRab Comparator [5-17M] Group and Menjugate Comparator [6-12W] Group.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered

intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Reporting group values	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group
Number of subjects	2276	2306	1985
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days)			

Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	1123	1137	967
Male	1153	1169	1018

Reporting group values	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Number of subjects	2005	2017	2057
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	976	2000	2000
Male	1029	17	57

Reporting group values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group
Number of subjects	1743	1788	1784
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			

Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	1000	1000	1000
Male	743	788	784

Reporting group values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group
Number of subjects	1838	1516	1548
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	1000	1000	1000
Male	838	516	548

Reporting group values	GSK257049 Group	Comparator Group	GSK257049 - GSK257049 [5-17M] Group
Number of subjects	8597	4364	1935
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			

From 65-84 years			
85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	8000	4000	1000
Male	597	364	935

Reporting group values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group
Number of subjects	1967	1637	1656
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	1000	1000	1000
Male	967	637	656

Reporting group values	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group
Number of subjects	2363	2382	1726
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	2000	2000	1000
Male	363	382	726

Reporting group values	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Number of subjects	1731	442	438
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	1000	400	400
Male	731	42	38

Reporting group values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group
Number of subjects	530	569	104
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	500	500	100
Male	30	69	4

Reporting group values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group
Number of subjects	101	101	103
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	100	100	100
Male	1	1	3

Reporting group values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - Menjugate [6-12W] Group	GSK257049 - Menjugate [5-17M] Group
Number of subjects	545	639	182
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	500	600	100
Male	45	39	82

Reporting group values	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group
Number of subjects	214	465	546
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	200	400	500
Male	14	65	46

Reporting group values	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group
Number of subjects	156	420	95
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	100	400	90
Male	56	20	5

Reporting group values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Number of subjects	134	641	639
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	100	600	600
Male	34	41	39

Reporting group values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group
Number of subjects	608	625	2447
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	600	600	2000
Male	8	25	447

Reporting group values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group
Number of subjects	2472	1825	1837
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	2000	1000	1000
Male	472	825	837

Reporting group values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group
Number of subjects	605	617	2976
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	600	600	2000
Male	5	17	976

Reporting group values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group
Number of subjects	2972	2180	2178
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	2000	2000	2000
Male	972	180	178

Reporting group values	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group
Number of subjects	2681	2719	1966
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	2000	2000	1000
Male	681	719	966

Reporting group values	GSK257049 - Menjugate [6-12W] Group	GSK257049 Group	GSK257049 - GSK257049 Group
Number of subjects	1996	84	33
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	1000	80	30
Male	996	4	3

Reporting group values	GSK257049 - Menjugate Group	Comparator Group	GSK257049 - GSK257049 [5-17M] Group
Number of subjects	35	41	273
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	30	40	200
Male	5	1	73

Reporting group values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group
Number of subjects	297	230	208
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	200	200	200
Male	97	30	8

Reporting group values	GSK257049 - GSK257049 Group	GSK257049 - Menjugate Group	Comparator Group
Number of subjects	51	54	48
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	50	54	48
Male	1	0	0

Reporting group values	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group
Number of subjects	277	304	232
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	277	304	232
Male	0	0	0

Reporting group values	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Number of subjects	211	48	50
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	211	48	50
Male	0	0	0

Reporting group values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group
Number of subjects	48	47	1509
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male			
Units: Participants			
Female	48	47	1509
Male	0	0	0

Reporting group values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group
Number of subjects	1500	1116	1118
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Age Continuous Units: Months			
arithmetic mean	10	10	10
standard deviation	± 3	± 3	± 3
Sex: Female, Male Units: Participants			
Female			
Male	0	0	0

End points reporting groups

Reporting group title	GSK257049 [5-17M] Group

Reporting group description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by either a booster dose of the same GSK257049 vaccine or a dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Reporting group title	GSK257049 [6-12W] Group

Reporting group description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by either a booster dose of the GSK257049 and Polio Sabin™ vaccines or a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Reporting group title	VeroRab Comparator [5-17M] Group

Reporting group description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the VeroRab® vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Reporting group title	Menjugate Comparator [6-12W] Group

Reporting group description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of Menjugate® vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 12. All vaccines have been administered intramuscularly in the left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group

Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 Group
Subject analysis set type	Per protocol

Subject analysis set description:

For the purpose of the analysis, GSK257049 [5-17M] and GSK257049 [6-12W] groups have been pooled into a single group.

Subject analysis set title	Comparator Group
Subject analysis set type	Per protocol

Subject analysis set description:

For the purpose of the analysis, VeroRab Comparator [5-17M] and Menjugate Comparator [6-12W] groups have been pooled into a single group.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered

intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster

dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of

Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose

primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered

intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose

primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 [5-17M] Group and GSK257049 [6-12W] Group.

Subject analysis set title	GSK257049 -GSK257049 Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 -GSK257049 [5-17M] Group and GSK257049 -GSK257049 [6-12W] Group.

Subject analysis set title	GSK257049 - Menjugate Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 - Menjugate [5-17M] Group and GSK257049 - Menjugate [6-12W] Group.

Subject analysis set title	Comparator Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled Group between VeroRab Comparator [5-17M] Group and Menjugate Comparator [6-12W] Group.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 -GSK257049 Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 -GSK257049 [5-17M] Group and GSK257049 -GSK257049 [6-12W] Group.

Subject analysis set title	GSK257049 - Menjugate Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled group between GSK257049 - Menjugate [5-17M] Group and GSK257049 - Menjugate [6-12W] Group.

Subject analysis set title	Comparator Group
Subject analysis set type	Per protocol

Subject analysis set description:

Pooled Group between VeroRab Comparator [5-17M] Group and Menjugate Comparator [6-12W] Group.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group

Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - GSK257049 [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of the same GSK257049 vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 - Menjugate [5-17M] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Subject analysis set title	GSK257049 -GSK257049 [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of the GSK257049 and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Subject analysis set title	GSK257049 - Menjugate [6-12W] Group
Subject analysis set type	Per protocol

Subject analysis set description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Primary: Rate of first or only clinical episode of Plasmodium falciparum (P. falciparum) malaria infection (CPFMI), or clinical malaria episode of Primary Case Definition (CPFMI-PCD)

End point title	Rate of first or only clinical episode of Plasmodium falciparum (P. falciparum) malaria infection (CPFMI), or clinical malaria episode of Primary Case Definition (CPFMI-PCD)[1]

End point description:

A CPFMI-PCD was defined as an episode of malaria for which P. falciparum asexual parasitemia was greater than (>) 5000 parasites per microliter (µL) accompanied by the presence of fever [axillary temperature greater than or equal to (≥) 37.5°C] at the time of presentation AND occurring in a child who is unwell and brought for treatment to a healthcare facility OR a case of malaria meeting the primary case definition of severe malaria disease. The time to first or only CPFMI-PCD is expressed in terms of rate of first or only CPFMI (RfoCPFMI), that is person-year rate in each group (n/T). Analysis for this outcome was solely performed on subjects in the 5-17 months age category.

End point type	Primary

End point timeframe:

From Month 2.5 to Month 14

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	GSK257049 [5-17M] Group	VeroRab Comparator [5-17M] Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2830	1466		
Units: events per person-year				
number (not applicable)	0.435	0.833		

Statistical analyses

Statistical analysis title	RfoCPFMI comparison

Statistical analysis description:

The analysis aimed to compare RfoCPFMI between groups over the Months 2.5-14 time period. Using RfoCFPMI, a Cox regression model was used to evaluate vaccine efficacy (VE) allowing for adjustment by factors. VE was calculated as 1 minus [Hazard Ratio (HR) in GSK257049 [5-17M] Group (HR1) divided by HR in control VeroRab Comparator [5-17M] Group (HR2)]; i. e. 1 - (HR1/HR2).

Comparison groups	GSK257049 [5-17M] Group v VeroRab Comparator [5-17M] Group
Number of subjects included in analysis	4296
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Vaccine efficacy
Point estimate	55.8
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	50.6
upper limit	60.4

Primary: Rate of first or only clinical episode of P. falciparum malaria infection (CPFMI), or clinical malaria episode of Primary Case Definition (CPFMI-PCD)

End point title	Rate of first or only clinical episode of P. falciparum malaria infection (CPFMI), or clinical malaria episode of Primary Case Definition (CPFMI-PCD)[2]

End point description:

A CPFMI-PCD was defined as an episode of malaria for which P. falciparum asexual parasitemia > 5000 parasites/µL was accompanied by the presence of fever (axillary temperature ≥ 37.5°C) at the time of presentation AND occurring in a child who is unwell and brought for treatment to a healthcare facility OR a case of malaria meeting the primary case definition of severe malaria disease. The time to first or only CPFMI-PCD is expressed in terms of rate of first or only CPFMI (RfoCPFMI), that is, person-year rate in each group (n/T). Analysis for this outcome was solely performed on subjects in the 6-12 weeks (6-12W) age category.

End point type	Primary

End point timeframe:

From Month 2.5 to Month 14

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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	GSK257049 [6-12W] Group	Menjugate Comparator [6-12W] Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3995	2008		
Units: events per person-year				
number (not applicable)	0.367	0.484		

Statistical analyses

Statistical analysis title	RfoCPFMI comparison

Statistical analysis description:

The analysis aimed to compare RfoCPFMI between groups over the Months 2.5-14 time period. Using RfoCFPMI, a Cox regression model was used to evaluate vaccine efficacy (VE) allowing for adjustment by factors. VE was calculated as 1 minus [Hazard Ratio (HR) in GSK257049 [6-12W] Group (HR1) divided by HR in control Menjugate Comparator [6-12W] Group (HR2)]; i. e. 1 - (HR1/HR2).

Comparison groups	GSK257049 [6-12W] Group v Menjugate Comparator [6-12W] Group
Number of subjects included in analysis	6003
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Vaccine efficacy
Point estimate	31.315
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	23.556
upper limit	38.286

Secondary: Rate of all episodes of P. falciparum clinical malaria infection (CPFMI) of PCD and of secondary case definitions (SCD) 1, SCD 2 and SCD 3

End point title	Rate of all episodes of P. falciparum clinical malaria infection (CPFMI) of PCD and of secondary case definitions (SCD) 1, SCD 2 and SCD 3

End point description:

PCD=malaria episode with P. falciparum asexual parasitemia (PFAP) > 5000 parasites/µL accompanied by fever and occurring in a child unwell brought for treatment to a healthcare facility or a case of malaria meeting the PCD of severe malaria disease. SCD1=malaria episode with PFAP > 0 and fever at time of presentation or history of fever within 24h of presentation in a subject unwell brought for treatment to a healthcare facility. SCD2=malaria episode with PFAP > 500 parasites/µL and fever at

time of presentation in a subject unwell brought for treatment to a healthcare facility. SCD3=malaria episode with PFAP > 20.000 parasites/µL and fever at time of presentation in a subject unwell and brought for treatment to a healthcare facility. Time to all CPFMI episodes is expressed as person-year rate in each group (n/T). Results are uncorrected for double enrollment of 1 subject receiving GSK257049 vaccine.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 14

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2830	3995	1466	2008
Units: events per person-year				
number (not applicable)				
PCD	0.735	0.639	1.468	0.908
SCD1	1.224	0.989	2.312	1.403
SCD2	0.847	0.736	1.628	1.031
SCD3	0.625	0.515	1.244	0.731

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of PCD, overall and by center

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of PCD, overall and by center

End point description:

PCD = malaria episode with PFAP > 5000 parasites/µL accompanied by fever and occurring in a child unwell brought for treatment to a healthcare facility or a case of malaria meeting the PCD of severe malaria disease (see below endpoints on severe malaria for details). Time to all CPFMI episodes is expressed as person-year rate in each group (n/T). Results are by center and across centers, and are uncorrected for double enrollment of 1 subject receiving GSK257049 vaccine.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4557	3996	2328	2007
Units: events per person-year				
number (not applicable)				
PCD – Agogo	0.56	0.64	1.16	0.79

PCD – Bagamoyo	0.1	0.08	0.28	0.14
PCD – Kilifi	0.01	0.04	0.04	0.02
PCD – Kintampo	1.01	1.53	1.85	1.49
PCD – Kombewa	1.21	0.94	1.87	1.32
PCD – Korogwe	0.04	0.03	0.11	0.05
PCD – Lambarene	0.11	0.11	0.2	0.12
PCD – Lilongwe	0.2	0.3	0.32	0.5
PCD – Manhica	0	0.1	0	0.12
PCD – Nanoro	1.42	1.93	2.4	2.39
PCD – Siaya	2.01	2.03	3.31	2.75
PCD – Across	0.69	0.71	1.17	0.92

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of SCD1, SCD2 and SCD3 (overall)

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of SCD1, SCD2 and SCD3 (overall)

End point description:

SCD1 = malaria episode with PFAP > 0 and fever at time of presentation or history of fever within 24h of presentation in a subject unwell brought for treatment to a healthcare facility. SCD2 = malaria episode with PFAP > 500 parasites/µL and fever at time of presentation in a subject unwell brought for treatment to a healthcare facility. SCD3 = malaria episode with PFAP > 20.000 parasites/µL and fever at time of presentation in a subject unwell and brought for treatment to a healthcare facility. Time to all CPFMI episodes is expressed as person-year rate in each group (n/T). Results are across centers, and are uncorrected for double enrollment of 1 subject receiving GSK257049 vaccine.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4557	3996	2328	2007
Units: events per person-year				
number (not applicable)				
SCD1	1.09	1.09	1.78	1.42
SCD2	0.78	0.81	1.3	1.04
SCD3	0.59	0.58	1.01	0.76

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of primary case definition (PCD), by centers and across centers

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of primary case definition (PCD), by centers and across centers[3]

End point description:

CPFMI of PCD = episode of malaria for which PFAP > 5000 parasites/µL accompanied by presence of fever (axillary temperature ≥ 37.5°C at time of presentation) AND occurring in a child unwell brought for treatment to a healthcare facility OR a case of malaria meeting the PCD of severe malaria disease. Time to all CPFMI episodes is expressed as person-year rate in each group (n/T). Results are presented by center and across centers.

End point type	Secondary

End point timeframe:

From Month 2.5 up to study End (with a median follow-up time post-Dose 1 of 48 months for 5-17M groups and 38 months for 6-12W groups)

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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: events per person-year				
number (not applicable)				
PCD – Kilifi	0.08	0.04	0.02	0.03
PCD – Korogwe	0.1	0.09	0.04	0.05
PCD – Lambarene	0.23	0.17	0.15	0.15
PCD – Bagamoyo	0.27	0.15	0.16	0.21
PCD – Lilongwe	0.23	0.42	0.09	0.2
PCD – Agogo	1.01	0.84	0.59	0.73
PCD – Kombewa	1.64	1.62	1.26	1.37
PCD – Kintampo	1.71	1.69	1.11	1.31
PCD – Manhica	0	0.2	0	0
PCD – Nanoro	2.69	3.14	1.95	2.18
PCD – Siaya	3.15	3.12	2.09	2.55
PCD – Across	1.14	1.08	0.79	0.9

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: events per person-year				
number (not applicable)				
PCD – Kilifi	0.06	0.04		
PCD – Korogwe	0.05	0.07		
PCD – Lambarene	0.1	0.18		
PCD – Bagamoyo	0.08	0.11		
PCD – Lilongwe	0.25	0.29		

PCD – Agogo	0.59	0.77		
PCD – Kombewa	1.37	1.37		
PCD – Kintampo	1.65	1.71		
PCD – Manhica	0.18	0.14		
PCD – Nanoro	2.59	2.79		
PCD – Siaya	2.43	2.67		
PCD – Across	0.86	0.95		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of Secondary Case Definition 1 (SCD1), across centers

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of Secondary Case Definition 1 (SCD1), across centers[4]

End point description:

CPFMI of SCD1 = malaria episode with PFAP >0 and fever at time of presentation or history of fever within 24h of presentation in a subject unwell brought for treatment to a healthcare facility. Time to all CPFMI episodes is expressed as person-year rate in each group (n/T). Results are presented across centers.

End point type	Secondary

End point timeframe:

From Month 2.5 up to study end (with a median follow-up time post-Dose 1 of 48 months for 5-17M groups and 38 months for 6-12W groups)

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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: events per person-year				
number (not applicable)	1.81	1.61	1.26	1.41

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: events per person-year				
number (not applicable)	1.29	1.43		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of Primary Case Definition (PCD) and Secondary Case Definition 1 (SCD1), across centers

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of Primary Case Definition (PCD) and Secondary Case Definition 1 (SCD1), across centers[5]

End point description:

CPFMI of PCD = episode of malaria for which PFAP > 5000 parasites/µL accompanied by the presence of fever (axillary temperature ≥ 37.5°C at time of presentation) AND occurring in a child unwell brought for treatment to a healthcare facility OR a case of malaria meeting the PCD of severe malaria disease. CPFMI of SCD1 = malaria episode with PFAP >0 and fever at time of presentation or history of fever within 24h of presentation in a subject unwell brought for treatment to a healthcare facility. Time to all CPFMI episodes is expressed as person-year rate in each group (n/T). Results are presented across centers.

End point type	Secondary

End point timeframe:

From Booster at Month 20 up to study end (with a median follow-up time post-Dose 1 of 48 months for 5-17M groups and 38 months for 6-12W groups)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2050	1762	2017	2057
Units: events per person-year				
number (not applicable)				
PCD	1.1	1.23	0.87	1.03
SCD1	1.82	1.8	1.39	1.65

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1743	1788		
Units: events per person-year				
number (not applicable)				
PCD	1.01	1.21		
SCD1	1.48	1.79		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of PCD and SCD1, across centers

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of PCD and SCD1, across centers[6]

End point description:

CPFMI of PCD = episode of malaria for which PFAP > 5000 parasites/µL accompanied by the presence of fever (axillary temperature ≥ 37.5°C at time of presentation) AND occurring in a child unwell brought for treatment to a healthcare facility OR a case of malaria meeting the PCD of severe malaria disease. CPFMI of SCD1 = malaria episode with PFAP > 0 and fever at time of presentation or history of fever within 24h of presentation in a subject unwell brought for treatment to a healthcare facility. Time to all CPFMI episodes is expressed as person-year rate in each group (n/T). Results are presented across centers.

End point type	Secondary

End point timeframe:

From Month 33 up to study end (with a median follow-up time post-Dose 1 of 48 months for 5-17M groups and 38 months for 6-12W groups)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	1864	1546	1784	1838
Units: events per person-year				
number (not applicable)				
PCD	1.1	1.29	1.01	1.1
SCD1	1.88	1.91	1.61	1.79

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1516	1548		
Units: events per person-year				
number (not applicable)				
PCD	1.18	1.31		
SCD1	1.73	1.92		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of PCD, by center and across centers

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of PCD, by center and across centers[7]

End point description:

CPFMI of PCD = episode of malaria for which PFAP > 5000 parasites/µL accompanied by the presence of fever (axillary temperature ≥ 37.5°C at time of presentation) AND occurring in a child unwell brought for treatment to a healthcare facility OR a case of malaria meeting the PCD of severe malaria disease. Time to all CPFMI episodes is expressed as person-year rate in each group (n/T). Results are presented by center and across centers.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 32

Notes:

[7] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: events per person-year				
number (not applicable)				
PCD – Kilifi	0.09	0.05	0.03	0.04
PCD – Korogwe	0.08	0.06	0.04	0.03
PCD – Lambarene	0.21	0.18	0.14	0.14
PCD – Bagamoyo	0.31	0.15	0.13	0.19
PCD – Lilongwe	0.29	0.47	0.11	0.22
PCD – Agogo	1.15	0.86	0.59	0.75
PCD – Kombewa	1.67	1.55	1.12	1.29
PCD – Kintampo	1.87	1.6	1.08	1.17
PCD – Manhica	0	0.15	0	0
PCD – Nanoro	2.45	2.92	1.42	1.67
PCD – Siaya	3.25	3.09	1.91	2.46
PCD – Across	1.15	1.03	0.68	0.81

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: events per person-year				
number (not applicable)				
PCD – Kilifi	0.06	0.04		
PCD – Korogwe	0.02	0.06		
PCD – Lambarene	0.1	0.18		
PCD – Bagamoyo	0.08	0.11		
PCD – Lilongwe	0.27	0.32		
PCD – Agogo	0.56	0.72		
PCD – Kombewa	1.28	1.25		
PCD – Kintampo	1.52	1.6		
PCD – Manhica	0.15	0.12		
PCD – Nanoro	2.27	2.53		

PCD – Siaya	2.41	2.54		
PCD – Across	0.8	0.88		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of Secondary Case Definition 1 (SCD1)

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of Secondary Case Definition 1 (SCD1)[8]

End point description:

CPFMI of SCD1 = malaria episode with PFAP > 0 and fever at time of presentation or history of fever within 24h of presentation in a subject unwell brought for treatment to a healthcare facility. Time to all episodes of CPFMI is expressed as a rate of all CPFMI (RaCPFMI), that is, person-year rate in each group (n/T).

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 32

Notes:

[8] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: events per person-year				
number (not applicable)	1.78	1.54	1.1	1.24

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: events per person-year				
number (not applicable)	1.19	1.33		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of

Primary Case Definition (PCD) and Secondary Case Definition 1 (SCD1)

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of Primary Case Definition (PCD) and Secondary Case Definition 1 (SCD1)[9]

End point description:

CPFMI of PCD = episode of malaria for which PFAP > 5000 parasites/µL accompanied by the presence of fever (axillary temperature ≥ 37.5°C at time of presentation) AND occurring in a child unwell brought for treatment to a healthcare facility OR a case of malaria meeting the PCD of severe malaria disease.
CPFMI of SCD1 = malaria episode with PFAP > 0 and fever at time of presentation or history of fever within 24h of presentation in a subject unwell brought for treatment to a healthcare facility. Time to all episodes of CPFMI is expressed as a rate of all CPFMI (RaCPFMI), that is, person-year rate in each group (n/T).

End point type	Secondary

End point timeframe:

From Booster at Month 20 up to Month 32

Notes:

[9] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2050	1762	2017	2057
Units: events per person-year				
number (not applicable)				
PCD	1.1	1.2	0.72	0.96
SCD1	1.74	1.74	1.14	1.48

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1743	1788		
Units: events per person-year				
number (not applicable)				
PCD	0.91	1.15		
SCD1	1.35	1.72		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with severe PFMI (SPFMI) of PCD, SCD1, SCD2 and SCD3, across centers

End point title	Percentage of subjects with severe PFMI (SPFMI) of PCD, SCD1, SCD2 and SCD3, across centers

End point description:

SPFMI of PCD = PFMI > 5000 parasites/µL, at least one severity marker and no co-morbidity diagnosis.

SPFMI of SCD1 = PFMI >5000 parasites/µL and with one or more severity marker. SPFMI of SCD2 = PFMI >0 with one or more severity marker and without co-morbidity diagnosis. SPFMI of SCD3 = PFMI >5000 parasites/µL, with one or more severity marker, and without co-morbidity or HIV. Severity markers = prostration; respiratory distress; Blantyre score ≤ 2; ≥ 2 seizures in 24 h prior to admission, emergency room and hospitalisation; hypoglycaemia < 2.2 mmol/L; acidosis BE ≤ -10.0 mmol/L,l < 5.0 mmol/L; anaemia<5.0 g/dL. Comorbidities = radiographically proven pneumonia; meningitis; positive blood culture on a blood culture taken within 72 h of admission; gastroenteritis with dehydration. Analysis was performed in a pooled manner across age categories. Results presented are uncorrected for double enrollment of one subject in 5-17 months age category receiving GSK257049 vaccine.

End point type	Secondary

End point timeframe:

From Month 2.5 up to the time when 250 subjects were diagnosed with severe malaria of PCD, SCD1, SCD2 and SCD3 (up to the Month 14 time point for each age category or date of booster dose, whichever occurred first)

End point values	GSK257049 Group	Comparator Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8597	4364		
Units: Percentage of subjects				
number (not applicable)				
PCD	0.019	0.03		
SCD1	0.023	0.036		
SCD2	0.023	0.034		
SCD3	0.019	0.03		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with severe PFMI (SPFMI) of PCD and SCD1.

End point title	Percentage of subjects with severe PFMI (SPFMI) of PCD and SCD1.

End point description:

SPFMI of PCD = PFMI>5000 parasites/µL, at least one severity marker and no co-morbidity diagnosis. SPFMI of SCD1 = PFMI>5000 parasites/µL and with one or more severity marker. Severity markers = prostration; respiratory distress; Blantyre score ≤ 2; ≥ 2 seizures in 24h prior to admission, emergency room and hospitalisation; hypoglycaemia<2.2 mmol/L; acidosis BE ≤ -10.0 mmol/L,l ≥ 5.0 mmol/L; anaemia<5.0 g/dL. Comorbidities = radiographically proven pneumonia; meningitis; positive blood culture on a blood culture taken within 72h of admission; gastroenteritis with dehydration. SPFMI of SCD1 = PFMI>5000 parasites/µL and with one or more severity marker. Severity markers = prostration; respiratory distress; Blantyre score ≤ 2; ≥ 2 seizures in 24h prior to admission, emergency room and hospitalisation; hypoglycaemia<2.2 mmol/L; acidosis BE ≤ -10.0 mmol/L,l ≥ 5.0 mmol/L; anaemia<5.0 g/dL. Results presented are uncorrected for double enrollment of one subject in 5-17 months age category.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 14

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2830	3995	1466	2008
Units: Percentage of subjects				
number (not applicable)				
SPFMI PCD	2.0	1.5	3.8	2.3
SPFMI SCD1	2.6	1.6	4.9	2.5

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with severe PFMI (SPFMI) of PCD and SCD1 .

End point title	Percentage of subjects with severe PFMI (SPFMI) of PCD and SCD1 .

End point description:

SPFMI of PCD = PFMI>5000 parasites/µL, at least one severity marker and no co-morbidity diagnosis. SPFMI of SCD1 = PFMI>5000 parasites/µL and with one or more severity marker. Severity markers = prostration; respiratory distress; Blantyre score ≤ 2; ≥ 2 seizures in 24h prior to admission, emergency room and hospitalisation; hypoglycaemia<2.2 mmol/L; acidosis BE ≤ -10.0 mmol/L,l ≥ 5.0 mmol/L; anaemia<5.0 g/dL. Comorbidities = radiographically proven pneumonia; meningitis; positive blood culture on a blood culture taken within 72h of admission; gastroenteritis with dehydration. SPFMI of SCD1 = PFMI>5000 parasites/µL and with one or more severity marker. Severity markers = prostration; respiratory distress; Blantyre score ≤ 2; ≥ 2 seizures in 24h prior to admission, emergency room and hospitalisation; hypoglycaemia<2.2 mmol/L; acidosis BE ≤ -10.0 mmol/L,l ≥ 5.0 mmol/L; anaemia<5.0 g/dL. Results presented are uncorrected for double enrollment of one subject in 5-17 months age category.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20 at Booster

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4557	3996	2328	2007
Units: Percentage of subjects				
number (not applicable)				
SPFMI PCD	0.03	0.03	0.04	0.03
SPFMI SCD1	0.03	0.03	0.05	0.03

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with severe PFMI (SPFMI) of PCD and SCD1

End point title	Percentage of subjects with severe PFMI (SPFMI) of PCD and SCD1[10]

End point description:

SPFMI of PCD = PFMI >5000 parasites/µL, at least one severity marker and no co-morbidity diagnosis. SPFMI of SCD1 = PFMI >5000 parasites/µL and with one or more severity marker. Severity markers = prostration; respiratory distress; Blantyre score ≤ 2; ≥ 2 seizures in 24 h prior to admission, emergency room and hospitalisation; hypoglycaemia<2.2 mmol/L; acidosis BE ≤ -10.0 mmol/L,l ≥ 5.0 mmol/L; anaemia<5.0 g/dL. Comorbidities = radiographically proven pneumonia; meningitis; positive blood culture on a blood culture taken within 72 h of admission; gastroenteritis with dehydration. SPFMI of SCD1 = PFMI >5000 parasites/µL and with one or more severity marker. Severity markers = prostration; respiratory distress; Blantyre score ≤ 2; ≥ 2 seizures in 24 h prior to admission, emergency room and hospitalisation; hypoglycaemia<2.2 mmol/L; acidosis BE ≤ -10.0 mmol/L,l ≥ 5.0 mmol/L; anaemia<5.0 g/dL.

End point type	Secondary

End point timeframe:

From Month 2.5, from Month 20(booster), from Month 33 up to study end (median follow-up time of 48 months post-Dose 1 for 5-17M age category and of 38 months post-Dose 1 for 6-12W age category) and from Month 2.5 to Month 32 and from Month 20 to Month 32

Notes:

[10] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: Percentage of subjects				
number (not applicable)				
PCD, M2.5 to SE	0.06	0.05	0.04	0.06
PCD, M20 to SE	0.02	0.03	0.03	0.04
PCD, M33 to SE	0.01	0.01	0.01	0.02
PCD, M2.5 to M32	0.05	0.04	0.03	0.05
PCD, M20 to M32	0.02	0.02	0.02	0.02
SCD1, M2.5 to SE	0.07	0.06	0.05	0.07
SCD1, M20 to SE	0.03	0.03	0.03	0.04
SCD1, M33 to SE	0.01	0.01	0.01	0.02
SCD1, M2.5 to M32	0.06	0.05	0.04	0.06
SCD1, M20 to M32	0.02	0.02	0.02	0.03

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: Percentage of subjects				
number (not applicable)				
PCD, M2.5 to SE	0.04	0.04		
PCD, M20 to SE	0.02	0.03		
PCD, M33 to SE	0.01	0.01		
PCD, M2.5 to M32	0.04	0.04		
PCD, M20 to M32	0.01	0.02		

SCD1, M2.5 to SE	0.04	0.05		
SCD1, M20 to SE	0.02	0.03		
SCD1, M33 to SE	0.01	0.01		
SCD1, M2.5 to M32	0.04	0.04		
SCD1, M20 to M32	0.01	0.02		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with incident severe anaemia (ISA) and malaria hospitalization (MH) for case definitions (CD) considered

End point title	Percentage of subjects with incident severe anaemia (ISA) and malaria hospitalization (MH) for case definitions (CD) considered

End point description:

CD considered were CD1 for ISA and CD1 and CD2 for MH. ISA of CD1 was defined as a documented hemoglobin < 5.0 g/dL identified at clinical presentation to morbidity surveillance system in association with a P. falciparum parasitemia > 5000 parasites/µL. MH of CD1 was defined as a medical hospitalization with confirmed P. falciparum > 5000 parasites/µL. MH of CD2 was defined as a hospitalization which, in the judgment of the principal investigator, P. falciparum infection was the sole or a major contributing factor to the presentation. Results presented are uncorrected for double enrollment of one subject in 5-17 months age category receiving GSK257049 vaccine.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4557	3996	2328	2007
Units: Percentage of subjects				
number (not applicable)				
ISA CD1	0.01	0.01	0.01	0.01
MH CD1	0.05	0.04	0.09	0.05
MH CD2	0.06	0.05	0.1	0.06

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with incident severe anaemia (ISA), malaria hospitalization (MH) and fatal malaria (FM) for case definitions (CD) considered.

End point title	Percentage of subjects with incident severe anaemia (ISA), malaria hospitalization (MH) and fatal malaria (FM) for case definitions (CD) considered.[11]

End point description:

ISA CD considered were CD1, CD2 and CD3 (definitions mentioned in the previous outcome measure). MH CD considered were CD1 and CD2 (definitions mentioned in the previous outcome measure).FM CD considered were primary CD (PCD) and sedondary CDs 1 and 4 (SCD1 and SCD4). FM of PCD was defined as a case of severe malaria meeting the primary case definition of severe malaria disease with a fatal outcome. FM of SCD1 was defined as a case of severe malaria meeting the secondary case definition 1 severe malaria disease with a fatal outcome. FM of SCD4 was defined as a fatal case associated with International Classification Disease (ICD10) codes B50, B53 and/or B54. Code B50 corresponds to P. falciparum malaria including mixed infections of P. falciparum with any other Plasmodium species; Code B53 corresponds to other parasitologically confirmed malaria; Code B54 corresponds to unspecified malaria including clinically diagnosed malaria without parasitological confirmation.

End point type	Secondary

End point timeframe:

From Month 2.5 to up to study end (with a median follow-up time post-Dose 1 of 48 months for 5-17M groups and 38 months for 6-12W groups)

Notes:

[11] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: Percentage of subjects				
number (not applicable)				
ISA CD1	0.02	0.02	0.01	0.01
ISA CD2	0.02	0.02	0.01	0.02
ISA CD3	0.02	0.03	0.02	0.02
MH CD1	0.12	0.08	0.07	0.1
MH CD2	0.13	0.1	0.09	0.11
FM PCD	0	0	0	0
FM SCD1	0	0	0	0
FM SCD4	0	0	0	0

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: Percentage of subjects				
number (not applicable)				
ISA CD1	0.01	0.01		
ISA CD2	0.01	0.02		
ISA CD3	0.02	0.03		
MH CD1	0.06	0.07		
MH CD2	0.08	0.09		
FM PCD	0	0		
FM SCD1	0	0		
FM SCD4	0	0.01		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with incident severe anaemia (ISA), malaria hospitalization (MH) and fatal malaria (FM) for case definitions (CD) considered

End point title	Percentage of subjects with incident severe anaemia (ISA), malaria hospitalization (MH) and fatal malaria (FM) for case definitions (CD) considered[12]

End point description:

ISA CD considered were CD1, CD2 and CD3 (definitions mentioned in the previous outcome measure). MH CD considered were CD1 and CD2 (definitions mentioned in the previous outcome measure).FM CD considered were primary CD (PCD) and sedondary CDs 1 and 4 (SCD1 and SCD4). FM of PCD was defined as a case of severe malaria meeting the primary case definition of severe malaria disease with a fatal outcome. FM of SCD1 was defined as a case of severe malaria meeting the secondary case definition 1 severe malaria disease with a fatal outcome. FM of SCD4 was defined as a fatal case associated with International Classification Disease (ICD10) codes B50, B53 and/or B54. Code B50 corresponds to P. falciparum malaria including mixed infections of P. falciparum with any other Plasmodium species; Code B53 corresponds to other parasitologically confirmed malaria; Code B54 corresponds to unspecified malaria including clinically diagnosed malaria without parasitological confirmation.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 32

Notes:

[12] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: Percentage of subjects				
number (not applicable)				
ISA CD1	0.01	0.01	0.01	0.01
ISA CD2	0.02	0.01	0.01	0.01
ISA CD3	0.02	0.02	0.01	0.02
MH CD1	0.11	0.07	0.06	0.09
MH CD2	0.12	0.09	0.08	0.1
FM PCD	0	0	0	0
FM SCD1	0	0	0	0
FM SCD4	0	0	0	0

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: Percentage of subjects				
number (not applicable)				
ISA CD1	0.1	0.01		
ISA CD2	0.01	0.01		
ISA CD3	0.02	0.02		
MH CD1	0.05	0.06		
MH CD2	0.07	0.08		
FM PCD	0	0		
FM SCD1	0	0		
FM SCD4	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with prevalent parasitemia, prevalent gametocytemia and prevalent severe and moderate anemia

End point title	Percentage of subjects with prevalent parasitemia, prevalent gametocytemia and prevalent severe and moderate anemia

End point description:

Prevalent parasitemia (PP) was defined as a documented P. falciparum asexual parasite density > 0 identified at timing of assessment. Prevalent gametocytemia (PG) was defined as a documented P. falciparum gametocyte density > 0 identified at a cross sectional survey. Prevalent severe anemia (PSA) was defined as a documented hemoglobin < 5.0 g/dL identified at timing of assessment. Prevalent moderate anemia (PMA) was defined as a documented hemoglobin < 8.0 g/dL identified at at timing of assessment. Results presented are uncorrected for the double enrollment of one subject receiving RTS,S/AS01.

End point type	Secondary

End point timeframe:

At Month 20 (Booster)

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4140	3571	2100	1766
Units: Percentage of subjects				
number (not applicable)				
PP	0.07	0.07	0.11	0.08
PSA	0	0	0	0
PMA	0.03	0.04	0.03	0.04
PG	0.03	0	0.04	0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with prevalent parasitemia and prevalent severe and moderate anemia

End point title	Percentage of subjects with prevalent parasitemia and prevalent severe and moderate anemia[13]

End point description:

Prevalent parasitemia (PP) was defined as a documented P. falciparum asexual parasite density > 0 identified at timing of assessment. Prevalent severe anemia (PSA) was defined as a documented hemoglobin < 5.0 g/dL identified at timing of assessment. Prevalent moderate anemia (PMA) was defined as a documented hemoglobin < 8.0 g/dL identified at timing of assessment. Analysis was performed on subjects aged 5-17 months at enrollment. Study End (Early) corresponds to children whose Month 32 visit took place after 30 June 2012 and who had one cross-sectional visit at study end. These children's last study visit was relatively earlier, with a median follow-up time of 14 months post Month 32. Study End (Late) corresponds to children whose Month 32 visit took place before (and including) 30 June 2012, and who had 2 cross-sectional visits after Month 32. These children's last study visit was relatively later, with a median follow-up time of 17 months post Month 32).

End point type	Secondary

End point timeframe:

At Months 32, 44, at study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category) (early and late)

Notes:

[13] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	1979	1648	1935	1967
Units: Percentage of subjects				
number (not applicable)				
PP, Month 32	0.14	0.1	0.09	0.1
PSA, Month 32	0	0	0	0
PMA, Month 32	0.02	0.03	0.02	0.02
PP, Month 44	0.2	0	0.16	0.17
PSA, Month 44	0	0	0	0
PMA, Month 44	0.01	0	0.01	0.02
PP, SE (Early)	0.14	0.13	0.09	0.1
PSA, SE (Early)	0	0	0	0
PMA, SE (Early)	0.03	0.03	0.01	0.02
PP, SE (Late)	0.21	0	0.18	0.18
PSA, SE (Late)	0	0	0	0
PMA, SE (Late)	0.02	0	0.03	0.03

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1637	1656		
Units: Percentage of subjects				
number (not applicable)				
PP, Month 32	0.09	0.11		
PSA, Month 32	0	0		
PMA, Month 32	0.02	0.04		
PP, Month 44	0	0		
PSA, Month 44	0	0		
PMA, Month 44	0	0		
PP, SE (Early)	0.11	0.14		
PSA, SE (Early)	0	0		
PMA, SE (Early)	0.03	0.03		
PP, SE (Late)	0	0		
PSA, SE (Late)	0	0		
PMA, SE (Late)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with pneumonia, all-cause hospitalization and sepsis, as per case definitions assessed

End point title	Percentage of subjects with pneumonia, all-cause hospitalization and sepsis, as per case definitions assessed

End point description:

Pneumonia case definitions assessed are PCD and SCD 1, 2 and 3. Pneumonia of PCD was defined as cough or difficulty breathing AND tachypnea (≥ 50 breaths per minute < 1 year, ≥ 40 breaths per minute ≥ 1year) AND lower chest wall indrawing. Pneumonia of SCD1 was defined as pneumonia of PCD accompanied by chest X-ray (CXR) consolidation or pleural effusion on x-ray taken within 72 h of admission. Pneumonia of SCD2 was defined as pneumonia of PCD accompanied by consolidation or pleural effusion or other infiltrates on a chest x-ray taken within 72 h of admission. Pneumonia of SCD3 was defined as pneumonia of PCD accompanied by an oxygen saturation < 90%. All-cause hospitalization of PCD was defined as a medical hospitalization of any cause (excludes planned admissions for medical investigation/care or elective surgery and trauma). Sepsis cases were defined as a child with positive blood culture (CD1) or salmonella blood culture (CD2).

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4557	3996	2328	2007
Units: Percentage of subjects				
number (not applicable)				
Pneumonia PCD	0.03	0.04	0.03	0.04
Pneumonia SCD1	0.01	0.01	0	0.01
Pneumonia SCD2	0.02	0.03	0.02	0.03
Pneumonia SCD3	0	0.01	0.01	0.01
All-Cause Hospitalization PCD	0.15	0.18	0.19	0.19
Sepsis CD1	0.02	0.02	0.02	0.01
Sepsis CD2	0.01	0.01	0.01	0.01

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with fatal malaria (FM) and all-cause mortality (ACM) as per case definitions assessed

End point title	Percentage of subjects with fatal malaria (FM) and all-cause mortality (ACM) as per case definitions assessed

End point description:

Fatal malaria case definitions assessed were PCD and SCD1. Fatal malaria of PCD was defined as a case of severe malaria meeting the primary case definition of severe malaria disease (defined in a previous outcome measure) with a fatal outcome. Fatal malaria of SCD1 was defined as a case of severe malaria meeting the secondary case definition 1 severe malaria disease (defined previously) with a fatal outcome. All-cause mortality case definitions assessed were the case definitions (CD) 1 and 2. All-cause mortality of CD1 was defined as a fatality (of any cause) (including mortality in the community and in hospital). All-cause mortality of CD2 was defined as a fatality (medical cause) (including mortality in the community and in hospital), at the exclusion of trauma which may be diagnosed by verbal autopsy. Results presented are uncorrected for double enrollment of one subject in 5-17 months age category receiving GSK257049 vaccine.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4557	3996	2328	2007
Units: Percentage of subjects				
number (not applicable)				
Fatal Malaria PCD	0	0	0	0
Fatal Malaria SCD1	0	0	0	0
All-cause mortality CD1	0.01	0.01	0.01	0.01
All-cause mortality CD2	0.01	0.01	0.01	0.01

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with pneumonia, all-cause hospitalization/mortality and sepsis, as per case definitions assessed

End point title	Percentage of subjects with pneumonia, all-cause hospitalization/mortality and sepsis, as per case definitions assessed[14]

End point description:

Pneumonia of PCD was defined as cough or difficulty breathing (on history) AND tachypnea (>= 50 breaths per minute < 1 year, >= 40 breaths per minute >= 1year) AND lower chest wall indrawing,SCD1 was defined as pneumonia of PCD accompanied by chest X-ray (CXR) consolidation or pleural effusion on x-ray taken within 72 h of admission,SCD2 was defined as pneumonia of PCD accompanied by consolidation or pleural effusion or other infiltrates on a chest x-ray taken within 72 h of admission,SCD3 was defined as pneumonia of PCD accompanied by an oxygen saturation less than 90%.All-cause hospitalization of PCD was defined as a medical hospitalization of any cause (excluding planned admissions for medical investigation/care or elective surgery and trauma).All-cause mortality of CD1 was defined as a fatality (of any cause),of CD2 defined as a fatality (medical cause).Sepsis of CD1 was defined as a child with positive blood culture;CD2 defined as a child with positive salmonella blood culture.

End point type	Secondary

End point timeframe:

From Month 2.5 up to study end (with a median follow-up time post-Dose 1 of 48 months for 5-17M groups and 38 months for 6-12W groups)

Notes:

[14] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: Percentage of subjects				
number (not applicable)				
All-Cause Hospitalization PCD	0.24	0.24	0.21	0.22
Sepsis CD1	0.03	0.02	0.02	0.02
Sepsis CD2	0.02	0.01	0.01	0.01
Pneumonia PCD	0.03	0.05	0.04	0.03
Pneumonia SCD1	0.01	0.01	0.01	0.01
Pneumonia SCD2	0.02	0.03	0.03	0.02
Pneumonia SCD3	0.01	0.01	0	0
All-Cause Mortality CD1	0.01	0.01	0.01	0.01
All-Cause Mortality CD2	0.01	0.01	0.01	0.01

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: Percentage of subjects				
number (not applicable)				
All-Cause Hospitalization PCD	0.23	0.23		
Sepsis CD1	0.02	0.02		
Sepsis CD2	0.01	0.02		
Pneumonia PCD	0.05	0.05		
Pneumonia SCD1	0.01	0.01		
Pneumonia SCD2	0.03	0.03		
Pneumonia SCD3	0.01	0.01		
All-Cause Mortality CD1	0.02	0.02		
All-Cause Mortality CD2	0.02	0.02		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with blood transfusion, as per case definition assessed

End point title	Percentage of subjects with blood transfusion, as per case definition assessed[15]

End point description:

Blood transfusion case definition assessed was the case definition 1 (CD1). Blood transfusion of CD1 was defined as a child with inpatient admission with documented blood transfusion.

End point type	Secondary

End point timeframe:

From Month 2.5 up to study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[15] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: Percentage of subjects				
number (not applicable)	0.04	0.04	0.03	0.03

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: Percentage of subjects				
number (not applicable)	0.03	0.03		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of primary case definition (PCD), by gender and overall

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of primary case definition (PCD), by gender and overall[16]

End point description:

CPFMI of PCD = episode of malaria for which PFAP > 5000 parasites/µL accompanied by the presence of fever (axillary temperature ≥ 37.5°C at time of presentation) AND occurring in a child unwell brought for treatment to a healthcare facility OR a case of malaria meeting the PCD of severe malaria disease. Time to all episodes of CPFMI is expressed as a rate of all CPFMI (RaCPFMI), that is, person-year rate in each group (n/T). Analysis was performed on subjects aged 5-17 months and 6-12 weeks at enrollment. Results were presented by gender and overall.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 32

Notes:

[16] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2336	2007	2276	2306
Units: events per person-year				
number (not applicable)				
PCD Females	1.11	1.06	0.72	0.8
PCD Males	1.19	1.01	0.65	0.81
PCD Overall	1.15	1.03	0.68	0.81

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1985	2005		
Units: events per person-year				
number (not applicable)				
PCD Females	0.76	0.79		
PCD Males	0.83	0.96		
PCD Overall	0.8	0.88		

Statistical analyses

No statistical analyses for this end point

Secondary: Height, weight and mid upper arm circumference for age z-score (HAZ, WAZ and MUACZ).

End point title	Height, weight and mid upper arm circumference for age z-score (HAZ, WAZ and MUACZ).

End point description:

Anthropometry consisted of length/height for age z-score [HAZ] (children < 2 years length measure and children ≥ 2 years standing height measure), weight for age z-score [WAZ] and mid-upper arm circumference for age z-score [MUACZ] measurements, where a HAZ < -1,5 z-score, indicates growth deficit, while a HAZ between -1,0 and ± 1,0 z-score, indicates normal height. A WAZ ≤ -3 z-score indicates a very low weight for age, a WAZ > -3 and ≤ -2 z-score indicates a low weight for age, a WAZ > - 2 z-score indicates normal weight. A MUACZ < -2 z-score indicates children that are wasted, a MUACZ < - 3 z-score indicates severely wasted children.

End point type	Secondary

End point timeframe:

At Month 20 (Booster)

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5948	4358	2974	2179
Units: z-score				
arithmetic mean (standard deviation)				
HAZ	-1.6 (± 1)	-1.7 (± 1.1)	-1.6 (± 1)	-1.7 (± 1.2)
WAZ	-1 (± 1)	-0.9 (± 1)	-1 (± 1)	-0.9 (± 1)
MUACZ	-0.3 (± 0.9)	-0.1 (± 1)	-0.3 (± 0.9)	-0.1 (± 1)

Statistical analyses

No statistical analyses for this end point

Secondary: Height, weight and mid upper arm circumference for age z-score (HAZ, WAZ and MUACZ)

End point title	Height, weight and mid upper arm circumference for age z-score (HAZ, WAZ and MUACZ)[17]

End point description:

Anthropometry consisted of length/height for age z-score [HAZ] (children < 2 years length measure and children ≥ 2 years standing height measure), weight for age z-score [WAZ] and mid-upper arm circumference for age z-score [MUACZ] measurements, where a HAZ < -1,5 z-score, indicates growth deficit, while a HAZ between -1,0 and ± 1,0 z-score, indicates normal height. A WAZ ≤ -3 z-score indicates a very low weight for age, a WAZ > -3 and ≤ -2 z-score indicates a low weight for age, a WAZ > - 2 z-score indicates normal weight. A MUACZ < -2 z-score indicates children that are wasted, a MUACZ < - 3 z-score indicates severely wasted children. Note: The early study end refers to children whose last visit in the primary study phase (Month 32) was after 30 June 2012 and who by protocol had one cross-sectional study end and to late study end refers to children whose last visit in the primary study phase (Month 32) was after 30 June 2012 and who by protocol had one cross-sectional study end.

End point type	Secondary

End point timeframe:

At Months 32, 44, at study end (early and late) (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[17] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2392	1725	2363	2382
Units: z-score				
arithmetic mean (standard deviation)				
HAZ, Month 32	-1.4 (± 1.0)	-1.5 (± 1.1)	-1.3 (± 1.0)	-1.4 (± 1.0)
WAZ, Month 32	-1.0 (± 0.9)	-0.9 (± 1.0)	-0.9 (± 0.9)	-1.0 (± 0.9)
MUACZ, Month 32	-0.4 (± 0.8)	-0.4 (± 1.0)	-0.4 (± 0.9)	-0.4 (± 0.9)
HAZ, Month 44	-1.2 (± 1.0)	0 (± 0)	-1.1 (± 1.0)	-1.2 (± 0.9)
WAZ, Month 44	-0.9 (± 0.8)	0 (± 0)	-0.9 (± 0.9)	-1.0 (± 0.9)
MUACZ, Month 44	-0.6 (± 0.8)	0 (± 0)	-0.7 (± 0.8)	-0.7 (± 0.9)
HAZ, Study end Early	-1.3 (± 1.0)	-1.4 (± 1.0)	-1.3 (± 1.0)	-1.3 (± 1.0)
WAZ, Study end Early	-1.0 (± 0.8)	-0.9 (± 0.9)	-1.0 (± 0.8)	-1.0 (± 0.8)
MUACZ, Study end Early	-0.8 (± 0.8)	-0.5 (± 0.9)	-0.8 (± 0.9)	-0.8 (± 0.9)
HAZ, Study end Late	-1.1 (± 1.0)	0 (± 0)	-1.0 (± 0.9)	-1.1 (± 0.9)
WAZ, Study end Late	-1.0 (± 0.8)	0 (± 0)	-0.9 (± 0.9)	-1.0 (± 0.9)
MUACZ, Study end Late	-0.7 (± 0.8)	0 (± 0)	-0.7 (± 0.8)	-0.8 (± 0.9)

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1726	1731		
Units: z-score				
arithmetic mean (standard deviation)				
HAZ, Month 32	-1.5 (± 1.1)	-1.4 (± 1.1)		
WAZ, Month 32	-0.9 (± 1.0)	-0.9 (± 1.0)		
MUACZ, Month 32	-0.4 (± 0.9)	-0.3 (± 1.0)		
HAZ, Month 44	0 (± 0)	0 (± 0)		
WAZ, Month 44	0 (± 0)	0 (± 0)		

MUACZ, Month 44	0 (± 0)	0 (± 0)		
HAZ, Study end Early	-1.4 (± 1.0)	-1.4 (± 1.0)		
WAZ, Study end Early	-0.9 (± 0.9)	-0.9 (± 0.9)		
MUACZ, Study end Early	-0.5 (± 0.9)	-0.4 (± 0.9)		
HAZ, Study end Late	0 (± 0)	0 (± 0)		
WAZ, Study end Late	0 (± 0)	0 (± 0)		
MUACZ, Study end Late	0 (± 0)	0 (± 0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against Plasmodium falciparum circumsporozoite (anti-CS)

End point title	Antibody concentrations against Plasmodium falciparum circumsporozoite (anti-CS)

End point description:

Anti-CS antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA) and presented as geometric mean concentrations (GMCs), expressed in ELISA units per milliliter (EL.U/mL). The seropositivity cut-off for the endpoint was a GMC value ≥ 0.5 EL.U/mL. Results were assessed for the first 200 subjects enrolled in each study center.

End point type	Secondary

End point timeframe:

At Day 0 and at Month 3

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1036	1234	529	627
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Day 0	0.3 (0.3 to 0.3)	0.4 (0.4 to 0.4)	0.3 (0.3 to 0.3)	0.4 (0.4 to 0.5)
Anti-CS, Month 3	621 (591.5 to 651.9)	210.5 (198.2 to 223.6)	0.3 (0.3 to 0.3)	0.3 (0.3 to 0.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against P. falciparum circumsporozoite (anti-CS).

End point title	Antibody concentrations against P. falciparum circumsporozoite (anti-CS).

End point description:

Anti-CS antibody concentrations were determined by ELISA and presented as geometric mean

concentrations (GMCs), expressed in EL.U/mL. The seropositivity cut-off for the endpoint was a GMC value ≥ 0.5 EL.U/mL. Results were assessed for the first 200 HIV-infected subjects enrolled in each study center. HIV infection was confirmed if present at screening or identified by morbidity surveillance, not infection confirmed by antibody testing after 18 months of age or by PCR, by the time of the analysis of results up to the Month 14 time point for the respective 5-17 months and 6-12 weeks age categories.

End point type	Secondary

End point timeframe:

At Day 0 and at Month 3

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	25	17	5
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Day 0	0.3 (0.2 to 0.5)	0.3 (0.2 to 0.4)	0.4 (0.3 to 0.5)	0.3 (0.3 to 0.3)
Anti-CS, Month 3	264.7 (137.5 to 509.6)	125.3 (58.1 to 270.3)	0.5 (0.2 to 1.7)	0.3 (0.3 to 0.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against P. falciparum circumsporozoite (anti-CS) .

End point title	Antibody concentrations against P. falciparum circumsporozoite (anti-CS) .[18]

End point description:

Anti-CS antibody concentrations were determined by ELISA and presented as geometric mean concentrations (GMCs), expressed in EL.U/mL. The seropositivity cut-off for the endpoint was a GMC value ≥ 0.5 EL.U/mL.

End point type	Secondary

End point timeframe:

At Months 20, 21 and 32

Notes:

[18] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	426	554	442	438
Units: EL.U/mL				
geometric mean (confidence interval 95%)				

Anti-CS, Agogo - Month 20	0.3 (0.3 to 0.4)	0.3 (0.2 to 0.3)	34.1 (24.0 to 48.3)	52.1 (41.3 to 65.7)
Anti-CS, Agogo - Month 21	0.3 (0.2 to 0.3)	0.3 (0.2 to 0.3)	265.0 (220.9 to 317.9)	48.3 (37.6 to 61.9)
Anti-CS, Agogo - Month 32	0.3 (0.2 to 0.3)	0.3 (0.3 to 0.4)	46.3 (34.8 to 61.6)	28.8 (21.8 to 37.9)
Anti-CS, Bagamoyo - Month 20	0.3 (0.3 to 0.3)	0.3 (0.2 to 0.3)	26.6 (14.2 to 49.9)	23.1 (11.1 to 47.8)
Anti-CS, Bagamoyo - Month 21	0.6 (0.2 to 1.4)	0.3 (0.2 to 0.4)	306.6 (206.5 to 455.4)	31.8 (19.4 to 52.2)
Anti-CS, Bagamoyo - Month 32	0.3 (0.3 to 0.3)	0.3 (0.3 to 0.3)	44.6 (27.2 to 73.3)	16.9 (10.2 to 27.9)
Anti-CS, Kilifi - Month 20	0.3 (0.3 to 0.3)	0.3 (0.2 to 0.3)	34.3 (26.3 to 44.7)	33.1 (26.3 to 41.6)
Anti-CS, Kilifi - Month 21	0.3 (0.3 to 0.3)	0.3 (0.3 to 0.3)	308.4 (251.8 to 377.7)	24.3 (18.1 to 32.8)
Anti-CS, Kilifi - Month 32	0.3 (0.2 to 0.4)	0.3 (0.3 to 0.3)	59.4 (45.7 to 77.2)	14.9 (11.0 to 20.2)
Anti-CS, Kintampo - Month 20	0.4 (0.3 to 0.5)	0.3 (0.3 to 0.4)	50.8 (37.2 to 69.5)	36.6 (26.4 to 50.7)
Anti-CS, Kintampo - Month 21	0.3 (0.2 to 0.3)	0.3 (0.3 to 0.4)	266.8 (188.9 to 377.0)	41.2 (31.2 to 54.6)
Anti-CS, Kintampo - Month 32	0.4 (0.3 to 0.5)	0.3 (0.3 to 0.3)	70.9 (55.2 to 90.9)	20.2 (14.3 to 28.5)
Anti-CS, Kombewa - Month 20	0.3 (0.3 to 0.4)	0.4 (0.3 to 0.5)	39.8 (29.9 to 53.0)	46.6 (33.2 to 65.3)
Anti-CS, Kombewa - Month 21	0.4 (0.3 to 0.4)	0.4 (0.3 to 0.5)	308.5 (252.4 to 377.0)	37.1 (26.7 to 51.5)
Anti-CS, Kombewa - Month 32	0.3 (0.3 to 0.4)	0.4 (0.3 to 0.4)	53.8 (40.3 to 71.7)	19.8 (14.1 to 27.7)
Anti-CS, Korogwe - Month 20	0.3 (0.3 to 0.3)	0.3 (0.2 to 0.3)	29.4 (21.4 to 40.4)	28.2 (22.5 to 35.3)
Anti-CS, Korogwe - Month 21	0.3 (0.2 to 0.3)	0.3 (0.2 to 0.4)	305.6 (266.4 to 350.5)	27.1 (20.7 to 35.5)
Anti-CS, Korogwe - Month 32	0.3 (0.2 to 0.3)	0.3 (0.2 to 0.3)	47.4 (37.5 to 59.9)	16.8 (13.1 to 21.7)
Anti-CS, Lambarene - Month 20	0.3 (0.2 to 0.3)	0.3 (0.3 to 0.3)	8.2 (5.8 to 11.6)	11.1 (7.0 to 17.6)
Anti-CS, Lambarene - Month 21	0.3 (0.2 to 0.3)	0.3 (0.2 to 0.3)	203.6 (155.1 to 267.3)	10.6 (6.6 to 16.8)
Anti-CS, Lambarene - Month 32	0.3 (0.2 to 0.4)	0.3 (0.2 to 0.3)	23.0 (15.6 to 33.9)	5.9 (3.6 to 9.9)
Anti-CS, Lilongwe - Month 20	0.4 (0.2 to 0.7)	0.3 (0.3 to 0.4)	45.9 (28.6 to 73.8)	22.2 (11.2 to 44.0)
Anti-CS, Lilongwe - Month 21	0.3 (0.2 to 0.4)	0.3 (0.2 to 0.4)	285.0 (228.5 to 355.4)	17.0 (8.1 to 35.7)
Anti-CS, Lilongwe - Month 32	0.3 (0.2 to 0.4)	0.3 (0.2 to 0.3)	45.6 (28.8 to 72.3)	12.7 (6.4 to 25.3)
Anti-CS, Nanoro - Month 20	0.3 (0.3 to 0.3)	0.3 (0.3 to 0.4)	57.2 (43.4 to 75.4)	61.8 (46.3 to 82.4)
Anti-CS, Nanoro - Month 21	0.3 (0.2 to 0.3)	0.3 (0.3 to 0.4)	520.5 (443.4 to 611.1)	71.1 (54.8 to 92.3)
Anti-CS, Nanoro - Month 32	0.3 (0.3 to 0.3)	0.5 (0.4 to 0.6)	69.2 (55.2 to 86.9)	35.0 (25.7 to 47.9)
Anti-CS, Siaya - Month 20	0.3 (0.3 to 0.4)	0.4 (0.3 to 0.5)	28.4 (18.4 to 44.0)	32.8 (21.6 to 50.1)
Anti-CS, Siaya - Month 21	0.3 (0.2 to 0.4)	0.4 (0.3 to 0.5)	398.1 (324.6 to 488.2)	36.4 (22.6 to 58.6)
Anti-CS, Siaya - Month 32	0.4 (0.3 to 0.5)	0.5 (0.4 to 0.7)	55.8 (41.4 to 75.3)	21.7 (13.4 to 35.1)
Anti-CS, Manhica - Month 20	0 (0 to 0)	0.3 (0.3 to 0.3)	0 (0 to 0)	0 (0 to 0)
Anti-CS, Manhica - Month 21	0 (0 to 0)	0.3 (0.2 to 0.3)	0 (0 to 0)	0 (0 to 0)

Anti-CS, Manhica - Month 32	0 (0 to 0)	0.3 (0.3 to 0.3)	0 (0 to 0)	0 (0 to 0)
Anti-CS, Overall sites - Month 20	0.3 (0.3 to 0.3)	0.3 (0.3 to 0.3)	34.4 (30.7 to 38.6)	35.4 (31.7 to 39.5)
Anti-CS, Overall sites - Month 21	0.3 (0.3 to 0.3)	0.3 (0.3 to 0.3)	318.2 (295.1 to 343.0)	34.2 (30.5 to 38.3)
Anti-CS, Overall sites - Month 32	0.3 (0.3 to 0.3)	0.3 (0.3 to 0.3)	52.4 (47.8 to 57.6)	19.3 (17.2 to 21.8)

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	530	569		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Agogo - Month 20	5.1 (3.4 to 7.6)	5.6 (3.8 to 8.4)		
Anti-CS, Agogo - Month 21	137.6 (95.0 to 199.3)	5.3 (3.5 to 8.0)		
Anti-CS, Agogo - Month 32	14.8 (9.5 to 23.1)	2.9 (1.9 to 4.5)		
Anti-CS, Bagamoyo - Month 20	6.9 (4.8 to 10.0)	7.6 (5.1 to 11.4)		
Anti-CS, Bagamoyo - Month 21	169.9 (129.8 to 222.5)	7.2 (4.5 to 11.6)		
Anti-CS, Bagamoyo - Month 32	14.4 (9.6 to 21.7)	3.7 (2.4 to 5.7)		
Anti-CS, Kilifi - Month 20	6.6 (4.6 to 9.6)	6.1 (4.0 to 9.4)		
Anti-CS, Kilifi - Month 21	229.3 (175.4 to 299.9)	5.3 (3.4 to 8.2)		
Anti-CS, Kilifi - Month 32	19.8 (14.1 to 27.8)	2.8 (1.8 to 4.4)		
Anti-CS, Kintampo - Month 20	3.8 (2.5 to 5.8)	3.7 (2.5 to 5.6)		
Anti-CS, Kintampo - Month 21	128.8 (95.7 to 173.4)	3.2 (2.0 to 5.0)		
Anti-CS, Kintampo - Month 32	13.3 (8.1 to 21.9)	2.2 (1.4 to 3.4)		
Anti-CS, Kombewa - Month 20	5.5 (3.6 to 8.4)	8.7 (5.8 to 13.0)		
Anti-CS, Kombewa - Month 21	146.3 (96.6 to 221.6)	9.2 (6.0 to 14.2)		
Anti-CS, Kombewa - Month 32	8.3 (4.8 to 14.3)	4.3 (2.8 to 6.6)		
Anti-CS, Korogwe - Month 20	7.9 (5.3 to 11.8)	8.1 (5.2 to 12.7)		
Anti-CS, Korogwe - Month 21	178.3 (141.2 to 225.1)	7.6 (4.8 to 11.9)		
Anti-CS, Korogwe - Month 32	19.6 (13.0 to 29.6)	4.9 (3.0 to 7.9)		
Anti-CS, Lambarene - Month 20	7.7 (5.1 to 11.6)	8.3 (5.8 to 12.1)		
Anti-CS, Lambarene - Month 21	251.3 (184.8 to 341.7)	7.4 (5.0 to 10.8)		
Anti-CS, Lambarene - Month 32	21.0 (13.9 to 31.7)	4.1 (2.9 to 5.8)		
Anti-CS, Lilongwe - Month 20	5.1 (3.2 to 8.3)	7.4 (4.7 to 11.5)		

Anti-CS, Lilongwe - Month 21	126.1 (92.7 to 171.5)	8.0 (5.2 to 12.1)		
Anti-CS, Lilongwe - Month 32	15.4 (9.3 to 25.4)	4.5 (3.1 to 6.6)		
Anti-CS, Nanoro - Month 20	2.7 (1.7 to 4.4)	3.2 (2.1 to 4.7)		
Anti-CS, Nanoro - Month 21	163.2 (121.4 to 219.4)	3.1 (2.0 to 4.6)		
Anti-CS, Nanoro - Month 32	11.9 (7.4 to 19.2)	2.8 (2.0 to 4.0)		
Anti-CS, Siaya - Month 20	7.0 (4.2 to 11.5)	8.9 (5.5 to 14.2)		
Anti-CS, Siaya - Month 21	171.5 (109.8 to 267.9)	8.4 (5.2 to 13.6)		
Anti-CS, Siaya - Month 32	23.6 (14.2 to 39.1)	5.5 (3.3 to 9.2)		
Anti-CS, Manhica - Month 20	12.3 (8.4 to 18.1)	14.7 (10.0 to 21.5)		
Anti-CS, Manhica - Month 21	260.2 (176.4 to 383.8)	12.3 (7.7 to 19.5)		
Anti-CS, Manhica - Month 32	25.4 (14.8 to 43.5)	6.8 (4.0 to 11.5)		
Anti-CS, Overall sites - Month 20	5.9 (5.2 to 6.7)	6.6 (5.8 to 7.5)		
Anti-CS, Overall sites - Month 21	169.9 (153.8 to 187.7)	6.2 (5.4 to 7.0)		
Anti-CS, Overall sites - Month 32	15.9 (13.8 to 18.3)	3.7 (3.3 to 4.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against P. falciparum circumsporozoite (anti-CS)

End point title	Antibody concentrations against P. falciparum circumsporozoite (anti-CS)[19]

End point description:

Anti-CS antibody concentrations were determined by ELISA and presented as geometric mean concentrations (GMCs), expressed in EL.U/mL. The seropositivity cut-off for the endpoint was a GMC value ≥ 0.5 EL.U/mL. Results for this endpoint were assessed for Agogo, Lilongwe and Siaya sites.

End point type	Secondary

End point timeframe:

At Month 44 and at study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[19] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	98	131	104	101
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Agogo - Month 44	0.3 (0.2 to 0.3)	0 (0 to 0)	27.7 (20.1 to 38.1)	17.9 (13.5 to 23.6)
Anti-CS, Agogo - Study end	0.3 (0.2 to 0.3)	0.3 (0.2 to 0.4)	23.2 (16.7 to 32.3)	17.2 (12.7 to 23.3)
Anti-CS, Lilongwe - Month 44	0.3 (0.2 to 0.3)	0 (0 to 0)	30.5 (21.4 to 43.5)	8.5 (4.5 to 15.9)
Anti-CS, Lilongwe - Study end	0.3 (0.3 to 0.3)	0.3 (0.2 to 0.3)	26.9 (18.3 to 39.5)	7.2 (4.1 to 12.5)
Anti-CS, Siaya - Month 44	0.5 (0.4 to 0.8)	0 (0 to 0)	41.4 (29.7 to 57.9)	21.2 (14.0 to 32.0)
Anti-CS, Siaya - Study end	0.4 (0.3 to 0.6)	0.4 (0.3 to 0.6)	27.4 (19.4 to 38.9)	15.8 (10.2 to 24.4)
Anti-CS, Overall - Month 44	0.3 (0.3 to 0.4)	0 (0 to 0)	33.0 (26.9 to 40.3)	16.8 (13.5 to 21.0)
Anti-CS, Overall - Study end	0.3 (0.3 to 0.4)	0.3 (0.3 to 0.4)	25.4 (20.6 to 31.2)	14.4 (11.4 to 18.1)

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	101	103		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Agogo - Month 44	0 (0 to 0)	0 (0 to 0)		
Anti-CS, Agogo - Study end	6.1 (3.2 to 11.4)	2.1 (1.3 to 3.4)		
Anti-CS, Lilongwe - Month 44	0 (0 to 0)	0 (0 to 0)		
Anti-CS, Lilongwe - Study end	10.9 (6.3 to 18.7)	2.8 (1.8 to 4.2)		
Anti-CS, Siaya - Month 44	0 (0 to 0)	0 (0 to 0)		
Anti-CS, Siaya - Study end	10.4 (6.1 to 17.7)	3.3 (1.9 to 5.6)		
Anti-CS, Overall - Month 44	0 (0 to 0)	0 (0 to 0)		
Anti-CS, Overall - Study end	8.9 (6.5 to 12.3)	2.6 (2.0 to 3.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against P. falciparum circumsporozoite (anti-CS), by tertile.

End point title	Antibody concentrations against P. falciparum circumsporozoite

	(anti-CS), by tertile.

End point description:

Anti-CS antibody concentrations were determined by ELISA and presented as geometric mean concentrations (GMCs), expressed in EL.U/mL. The seropositivity cut-off for the endpoint was a GMC value ≥ 0.5 EL.U/mL. Results were presented by tertiles of anti-CS responses in the first 200 participants per site, based on subjects assessed for vaccine efficacy results.

End point type	Secondary

End point timeframe:

At Month 3

End point values	GSK257049 - Menjugate [5-17M] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	545	639		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Tertile 1	264.15 (238.2 to 292.9)	78.45 (69.4 to 88.6)		
Anti-CS, Tertile 2	613.79 (598.3 to 629.7)	230.68 (224.7 to 236.8)		
Anti-CS, Tertile 3	1351.41 (1276.3 to 1431)	592.65 (557.8 to 629.6)		
Anti-CS, Across Tertiles	603.77 (563.6 to 646.8)	220.9 (204.1 to 239)		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of primary case definition (PCD), by tertile.

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of primary case definition (PCD), by tertile.[20]

End point description:

CPFMI of PCD = episode of malaria for which PFAP > 5000 parasites/µL accompanied by presence of fever (axillary temperature ≥ 37.5°C at time of presentation) AND occurring in a child unwell brought for treatment to a healthcare facility OR a case of malaria meeting the PCD of severe malaria disease. Time to all episodes of CPFMI is expressed as a rate of all CPFMI (RaCPFMI), that is, person-year rate in each group (n/T). RaCPFMI was calculated by tertile of anti-CS response post primary vaccination pooled across sites, on subjects in GSK257049-Menjugate Groups (5-17M; 6-12W) and Comparator Groups (5-17M; 6-12W), taking into account the first 200 participants per site.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 32

Notes:

[20] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - Menjugate [5-17M] Group	GSK257049 - Menjugate [6-12W] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	565	677	182	214
Units: events per person-year				
number (not applicable)				
Tertile 1	1.21	0.93	0.68	1.29
Tertile 2	1.21	0.93	0.78	0.7
Tertile 3	1.21	0.93	1.03	0.58

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against P. falciparum circumsporozoite (anti-CS), by tertile

End point title	Antibody concentrations against P. falciparum circumsporozoite (anti-CS), by tertile

End point description:

Anti-CS antibody concentrations were determined by ELISA and presented as geometric mean concentrations (GMCs), expressed in EL.U/mL. The seropositivity cut-off for the endpoint was a GMC value ≥ 0.5 EL.U/mL. Results were presented by tertiles of anti-CS responses in the first 200 participants per site, based on subjects assessed for vaccine efficacy results.

End point type	Secondary

End point timeframe:

At Month 21

End point values	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	465	546		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Tertile 1	138.15 (123.5 to 154.5)	47.99 (41.2 to 55.9)		
Anti-CS, Tertile 2	311.35 (303.4 to 319.6)	194.85 (189.9 to 200)		
Anti-CS, Tertile 3	675.24 (632.8 to 720.5)	479.44 (446.8 to 514.5)		
Anti-CS, Across Tertiles	307.93 (286.2 to 331.3)	165.31 (150 to 182.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of primary case definition (PCD), by tertile

End point title	Rate of all episodes of clinical P. falciparum malaria infection (CPFMI) of primary case definition (PCD), by tertile[21]

End point description:

CPFMI of PCD = episode of malaria for which PFAP > 5000 parasites/µL accompanied by presence of fever (axillary temperature ≥ 37.5°C at time of presentation) AND occurring in a child unwell brought for treatment to a healthcare facility OR a case of malaria meeting the PCD of severe malaria disease. Time to all episodes of CPFMI is expressed as a rate of all CPFMI (RaCPFMI), that is, person-year rate in each group (n/T). RaCPFMI was calculated by tertile of anti-CS response post booster vaccination pooled across sites, on subjects in R3R (5-17M; 6-12W) (or R3R below) and C3C (5-17M; 6-12W) (or C3C below) groups taking into account the first 200 participants per site.

End point type	Secondary

End point timeframe:

From Booster at Month 20 to Month 32

Notes:

[21] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	479	594	156	420
Units: events per person-year				
number (not applicable)				
Tertile 1	1.21	0.94	0.68	0.99
Tertile 2	1.21	0.94	0.68	0.84
Tertile 3	1.21	0.94	0.77	0.64

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against Hepatitis B surface antigen (anti-HBs).

End point title	Antibody concentrations against Hepatitis B surface antigen (anti-HBs).

End point description:

Antibody concentrations assessed by ELISA, were presented as geometric mean concentrations (GMCs), and expressed in milli-international units per milliliter (mIU/mL). The seropositivity and seroprotection cut-offs were ≥ 10 and 100 mIU/mL, respectively. Results were assessed for the first 200 subjects in each center.

End point type	Secondary

End point timeframe:

At Day 0 and at Month 3

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1029	1213	526	627
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, Day 0	166.3 (148 to 186.8)	8.6 (8 to 9.3)	168.6 (142.8 to 199.2)	8.5 (7.7 to 9.4)
Anti-HBs, Month 3	81567.7 (75442.7 to 88189.9)	13674.3 (12811.5 to 14595.3)	127.5 (108.8 to 149.4)	728.8 (643.6 to 825.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against Hepatitis B surface antigen

End point title	Antibody concentrations against Hepatitis B surface antigen

End point description:

Antibody concentrations as assessed by ELISA, were presented as geometric mean concentrations (GMCs), and expressed in mIU/mL. The seropositivity and seroprotection cut-offs were ≥ 10 and 100 mIU/mL, respectively. Results were assessed for the first 200 HIV-infected subjects enrolled in each study center. HIV infection was confirmed if present at screening or identified by morbidity surveillance, not infection confirmed by antibody testing after 18 months of age or by PCR, by the time of the analysis of results up to the Month 14 time point for the respective 5-17 months and 6-12 weeks age categories.

End point type	Secondary

End point timeframe:

At Day 0 and at Month 3

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	25	17	5
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, Day 0	98.6 (43.8 to 222)	7.5 (4.8 to 11.6)	63.6 (19.4 to 208.4)	5 (5 to 5)
Anti-HBs, Month 3	37476.5 (17766 to 79054.9)	1996.2 (561.6 to 7095.8)	37.1 (9.1 to 151.9)	197.2 (7.7 to 5081.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against Hepatitis B surface antigen (anti-HBs)

End point title	Antibody concentrations against Hepatitis B surface antigen (anti-HBs)

End point description:

Antibody concentrations as assessed by ELISA, were presented as geometric mean concentrations (GMCs), and expressed in mIU/mL. The seropositivity and seroprotection cut-offs were ≥ 6.2 and 100 mIU/mL, respectively. Results were assessed for the first 200 subjects in each center.

End point type	Secondary

End point timeframe:

At Months 20 and 21

End point values	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - GSK257049 [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	95	134		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, Month 20	5068.5 (3711.3 to 6922)	1532.5 (1240.6 to 1893.2)		
Anti-HBs, Month 21	95206.4 (72395.4 to 125204.9)	116458.1 (86865.7 to 156131.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers against poliomyelitis (anti-polio) type 1, 2 and 3

End point title	Antibody titers against poliomyelitis (anti-polio) type 1, 2 and

End point description:

Anti-Polio 1, 2 and 3 antibody titers were presented as geometric mean titers (GMTs). The seroprotection cut-off for the assay was an antibody titer ≥ 1:8.

End point type	Secondary

End point timeframe:

At Day 0 and at Month 3

Notes:

[22] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	GSK257049 [6-12W] Group	Menjugate Comparator [6-12W] Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	931	474		
Units: Titer				
geometric mean (confidence interval 95%)				
Anti-Polio 1, Day 0	47.4 (41.7 to 53.8)	43.3 (36.2 to 51.9)		
Anti-Polio 1, Month 3	334.9 (295.2 to 379.8)	417.6 (351.4 to 496.2)		
Anti-Polio 2, Day 0	38.6 (34.6 to 43.2)	40.3 (34.2 to 47.5)		
Anti-Polio 2, Month 3	372.1 (334.5 to 414.0)	450.8 (393.9 to 516.0)		
Anti-Polio 3, Day 0	9.4 (8.6 to 10.3)	9.1 (8.0 to 10.3)		
Anti-Polio 3, Month 3	80.0 (71.0 to 90.1)	95.9 (82.0 to 112.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms.

End point title	Number of subjects with any and grade 3 solicited local symptoms.

End point description:

Assessed solicited local symptoms included pain, redness and swelling. Any = the incidence of a particular symptom, regardless of intensity grade. Grade 3 pain = cried when limb was moved, spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 20 millimeters (mm) of injection site.

End point type	Secondary

End point timeframe:

During the 7-day (Days 0-6) post-primary vaccination period following each dose and across doses

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1479	1462	721	738
Units: Participants				
Any Pain, Dose 1	247	435	61	215
Grade 3 Pain, Dose 1	0	10	0	7
Any Redness, Dose 1	66	176	26	89
Grade 3 Redness, Dose 1	2	3	0	3
Any Swelling, Dose 1	140	227	77	125
Grade 3 Swelling, Dose 1	6	27	0	29
Any Pain, Dose 2	179	383	41	178
Grade 3 Pain, Dose 2	3	5	0	3

Any Redness, Dose 2	26	124	18	90
Grade 3 Redness, Dose 2	3	3	0	1
Any Swelling, Dose 2	140	228	50	128
Grade 3 Swelling, Dose 2	15	29	0	17
Any Pain, Dose 3	108	345	22	153
Grade 3 Pain, Dose 3	0	8	0	2
Any Redness, Dose 3	42	113	13	63
Grade 3 Redness, Dose 3	2	1	0	1
Any Swelling, Dose 3	134	185	35	111
Grade 3 Swelling, Dose 3	9	9	0	12
Any Pain, Across doses	401	705	105	342
Grade 3 Pain, Across doses	3	23	0	12
Any Redness, Across doses	122	292	49	163
Grade 3 Redness, Across doses	6	7	0	5
Any Swelling, Across doses	303	427	119	248
Grade 3 Swelling, Across doses	25	59	0	53

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms.

End point title	Number of subjects with any, grade 3 and related solicited general symptoms.

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite, fever [defined as axillary temperature equal to or above (≥) 37.5 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

During the 7-day (Days 0-6) post-primary vaccination period following each dose and across doses

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1479	1462	721	738
Units: Participants				
Any Drowsiness, Dose 1	91	164	27	65
Grade 3 Drowsiness, Dose 1	3	1	0	1
Related Drowsiness, Dose 1	33	88	8	26
Any Irritability, Dose 1	165	370	41	157
Grade 3 Irritability, Dose 1	0	10	0	3
Related Irritability, Dose 1	64	226	16	84
Any Loss of appetite, Dose 1	202	124	71	52
Grade 3 Loss of appetite, Dose 1	3	2	0	0

Related Loss of appetite, Dose 1	71	67	24	24
Any Fever, Dose 1	385	459	108	192
Grade 3 Fever, Dose 1	29	5	7	2
Related Fever, Dose 1	200	326	52	127
Any Drowsiness, Dose 2	99	135	37	55
Grade 3 Drowsiness, Dose 2	1	0	0	0
Related Drowsiness, Dose 2	61	74	26	15
Any Irritability, Dose 2	192	289	45	123
Grade 3 Irritability, Dose 2	2	7	0	0
Related Irritability, Dose 2	114	175	28	57
Any Loss of appetite, Dose 2	151	105	47	43
Grade 3 Loss of appetite, Dose 2	0	0	0	0
Related Loss of appetite, Dose 2	89	60	24	8
Any Fever, Dose 2	503	411	100	154
Grade 3 Fever, Dose 2	42	9	10	6
Related Fever, Dose 2	267	278	42	89
Any Drowsiness, Dose 3	97	124	29	44
Grade 3 Drowsiness, Dose 3	1	1	0	1
Related Drowsiness, Dose 3	52	49	16	19
Any Irritability, Dose 3	138	287	27	104
Grade 3 Irritability, Dose 3	1	3	0	2
Related Irritability, Dose 3	76	144	15	54
Any Loss of appetite, Dose 3	138	106	40	45
Grade 3 Loss of appetite, Dose 3	2	0	0	1
Related Loss of appetite, Dose 3	76	44	18	20
Any Fever, Dose 3	457	429	77	111
Grade 3 Fever, Dose 3	39	13	7	3
Related Fever, Dose 3	262	280	32	57
Any Drowsiness, Across doses	230	285	78	121
Grade 3 Drowsiness, Across doses	5	2	0	2
Related Drowsiness, Across doses	121	144	44	51
Any Irritability, Across doses	369	574	96	244
Grade 3 Irritability, Across doses	3	17	0	5
Related Irritability, Across doses	207	363	54	139
Any Loss of appetite, Across doses	398	243	132	104
Grade 3 Loss of appetite, Across doses	5	2	0	1
Related Loss of appetite, Across doses	206	128	61	41
Any Fever, Across doses	897	839	235	331
Grade 3 Fever, Across doses	105	26	24	11
Related Fever, Across doses	547	598	110	209

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms

End point title	Number of subjects with any and grade 3 solicited local symptoms[23]

End point description:

Assessed solicited local symptoms included pain, redness and swelling. Any = the incidence of a particular symptom, regardless of intensity grade. Grade 3 pain = cried when limb was moved, spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 20 millimeters (mm) of injection site.

End point type	Secondary

End point timeframe:

During the 7-day (Days 0-6) post-booster vaccination period

Notes:

[23] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	633	621	641	639
Units: Participants				
Any Pain	41	25	109	45
Grade 3 Pain	0	0	0	0
Any Redness	8	9	15	13
Grade 3 Redness	0	0	3	0
Any Swelling	30	43	42	35
Grade 3 Swelling	0	2	9	1

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	608	625		
Units: Participants				
Any Pain	59	29		
Grade 3 Pain	0	0		
Any Redness	9	12		
Grade 3 Redness	1	0		
Any Swelling	45	28		
Grade 3 Swelling	5	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms

End point title	Number of subjects with any, grade 3 and related solicited general symptoms[24]

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite, fever [defined as axillary temperature equal to or above (≥) 37.5 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

During the 7-day (Days 0-6) post-booster vaccination period

Notes:

[24] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	633	621	641	639
Units: Participants				
Any Drowsiness	21	15	55	22
Grade 3 Drowsiness	0	0	1	0
Related Drowsiness	13	5	34	10
Any Irritability	18	23	63	25
Grade 3 Irritability	0	0	1	0
Related Irritability	8	6	40	12
Any Loss of appetite	21	18	66	27
Grade 3 Loss of appetite	0	0	1	0
Related Loss of appetite	13	6	39	14
Any Fever	45	58	233	70
Grade 3 Fever	5	10	34	6
Related Fever	16	18	151	29

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	608	625		
Units: Participants				
Any Drowsiness	33	19		
Grade 3 Drowsiness	0	0		
Related Drowsiness	19	6		
Any Irritability	46	23		
Grade 3 Irritability	0	0		
Related Irritability	27	10		
Any Loss of appetite	45	27		
Grade 3 Loss of appetite	0	0		
Related Loss of appetite	26	8		
Any Fever	152	52		
Grade 3 Fever	9	7		

Related Fever	80	15		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of doses with seizures by diagnostic certainty level

End point title	Number of doses with seizures by diagnostic certainty level[25]

End point description:

Diagnostic certainty levels included: Level 1- Witnessed sudden loss of consciousness and generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations; Level 2- History of unconsciousness and generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations; Level 3- History of unconsciousness and other generalized motor manifestations; Level 4- Reported generalized convulsive seizure with insufficient evidence to meet the case definition; Level 5- Not a case of generalized convulsive seizure.

End point type	Secondary

End point timeframe:

During the 7-day (Days 0-6) post-booster vaccination period, at Month 20 + 7 Day (Days 0-6)

Notes:

[25] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2473	1827	2447	2472
Units: Doses				
Level 1	0	0	1	1
Level 2	1	1	5	2
Level 3	0	0	0	0
Level 4	0	0	1	0
Level 5	0	0	1	1

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1825	1837		
Units: Doses				
Level 1	1	0		
Level 2	3	0		
Level 3	0	0		
Level 4	0	0		
Level 5	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting mucocutaneous changes (all levels)

End point title	Number of subjects reporting mucocutaneous changes (all levels)[26]

End point description:

Levels of mucocutaneous changes reported were: cutaneous and mucosal change; cutaneous only change; mucosal only change; cutaneous change focused on the nappy/diaper area. Mucocutaneous changes results calculated based on the first 200 subjects in the 6-12 weeks age category in each study center were enrolled, and with available data (i.e. who received a booster dose).

End point type	Secondary

End point timeframe:

During the 30-day (Days 0-29) post-booster vaccination

Notes:

[26] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	614	605	617	
Units: Participants	59	64	47	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any meningitis and encephalitis serious adverse events (SAEs)

End point title	Number of subjects reporting any meningitis and encephalitis serious adverse events (SAEs)[27]

End point description:

Meningitis and encephalitis SAEs included: meningitis/encephalitis; meningitis/encephalitis viral; meningism; meningitis haemophilus; meningitis meningococcal; meningitis pneumococcal; meningitis tuberculous; encephalomyelitis.

End point type	Secondary

End point timeframe:

At Month 0 until study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[27] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2974	2179	2976	2972
Units: Participants	5	7	15	12

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2180	2178		
Units: Participants	7	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any meningitis and encephalitis SAEs

End point title	Number of subjects reporting any meningitis and encephalitis SAEs[28]

End point description:

Meningitis and encephalitis SAEs included: meningitis/encephalitis; meningitis haemophilus; meningitis meningococcal; meningitis tuberculous; encephalomyelitis.

End point type	Secondary

End point timeframe:

From Booster up to study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[28] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2702	1976	2681	2719
Units: Participants	0	3	4	4

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1966	1996		
Units: Participants	0	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any potential immune-mediated disorders (pIMDs)

End point title	Number of subjects reporting any potential immune-mediated disorders (pIMDs)[29]

End point description:

Potential immune-mediated diseases (pIMDs) are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune aetiology.

End point type	Secondary

End point timeframe:

From Month 0 up to study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[29] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2974	2179	2976	2972
Units: Participants	4	2	5	1

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2180	2178		
Units: Participants	3	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any unsolicited adverse events (AEs)

End point title	Number of subjects with any unsolicited adverse events (AEs)

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and 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. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Unsolicited AEs were calculated based on the first 200 subjects enrolled in each study center.

End point type	Secondary

End point timeframe:

Within the 30-day (Days 0-29) post-primary vaccination period

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1479	1462	721	738
Units: Participants	1273	1161	626	600

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs related to or leading to vaccination withdrawal.

End point title	Number of subjects with unsolicited AEs related to or leading to vaccination withdrawal.

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and 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. Related = AE assessed by the investigator as related to the vaccination. Unsolicited AEs were calculated based on the first 200 subjects enrolled in each study center.

End point type	Secondary

End point timeframe:

Within the 30-day (Days 0-29) post-primary vaccination period

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3997	4358	2003	2179
Units: Participants	399	578	72	231

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any unsolicited AEs

End point title	Number of subjects with any unsolicited AEs[30]

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and 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. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Unsolicited AEs were calculated based on the first 200 subjects enrolled in each study center.

End point type	Secondary

End point timeframe:

Within the 30-day (days 0-29) post-booster vaccination period

Notes:

[30] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	633	621	641	639
Units: Participants	215	240	232	205

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	608	625		
Units: Participants	231	239		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs related to or leading to vaccination withdrawal

End point title	Number of subjects with unsolicited AEs related to or leading to

	vaccination withdrawal

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and 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. Related = AE assessed by the investigator as related to the vaccination. Unsolicited AEs were calculated based on the subgroup of the first 200 subjects enrolled in each study center, who were reported with HIV infected status ((HIV status either as per general medical history taken at screening or as identified by morbidity surveillance).

End point type	Secondary

End point timeframe:

Within the 30-day (Days 0-29) post-primary and post-booster vaccination period in HIV-infected children

End point values	GSK257049 Group	GSK257049 - GSK257049 Group	GSK257049 - Menjugate Group	Comparator Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	84	33	35	41
Units: Participants				
Any AE(s), post-primary vaccination	13	0	0	3
Any AE(s), post-booster vaccination	0	2	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs related to or leading to vaccination withdrawal in the low-weight (LW) and very low-weight (VLW) category

End point title	Number of subjects with unsolicited AEs related to or leading to vaccination withdrawal in the low-weight (LW) and very low-weight (VLW) category

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and 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. Related = AE assessed by the investigator as related to the vaccination. Unsolicited AEs were calculated based on the subgroup of the first 200 subjects enrolled in each study center, who were reported with HIV infected status ((HIV status either as per general medical history taken at screening or as identified by morbidity surveillance). Low-weight subjects were defined as subjects whose weight for age z-score (WAZ) was > -3 and ≤ -2. Very low-weight subjects were defined as subjects whose weight for age z-score (WAZ) was ≤ -3.

End point type	Secondary

End point timeframe:

Within the 30-day (Days 0-29) post-primary vaccination period in HIV-infected children

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	695	221	364	126
Units: Participants				
Any AE(s), in LW	68	38	21	17
Any AE(s), in VLW	27	24	6	10

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs related to vaccination in the low-weight (LW) and very low-weight (VLW) category

End point title	Number of subjects with unsolicited AEs related to vaccination in the low-weight (LW) and very low-weight (VLW) category[31]

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and 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. Related = AE assessed by the investigator as related to the vaccination. Unsolicited AEs were calculated based on the subgroup of the first 200 subjects enrolled in each study center. Low-weight subjects were defined as subjects whose weight for age z-score (WAZ) was > -3 and ≤ -2. Very low-weight subjects were defined as subjects whose weight for age z-score (WAZ) was ≤ -3.

End point type	Secondary

End point timeframe:

Within the 30-day (Days 0-29) post-booster vaccination period

Notes:

[31] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	293	195	273	297
Units: Participants				
Any AE(s) in LW	0	0	4	1
Any AE(s) in VLW	1	1	5	0

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	230	208		
Units: Participants				
Any AE(s) in LW	2	0		

Any AE(s) in VLW	2	0		

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:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

From Month 0 up to Month 14

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5948	4358	2974	2179
Units: Participants	1040	782	634	419

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAEs

End point title	Number of subjects with SAEs

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

During the 30-day (Days 0-29) post-primary vaccination period

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5948	4358	2974	2179
Units: Participants	312	192	181	96

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:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

From Month 0 up to Month 20

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5948	4358	2974	2179
Units: Participants	1108	959	676	503

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAEs.

End point title	Number of subjects with SAEs.[32]

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

From Booster (at Month 20) up to study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[32] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2702	1976	2681	2719
Units: Participants	287	201	276	316

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1966	1996		
Units: Participants	180	193		

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) .[33]

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

From Month 0 up to study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[33] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2974	2179	2976	2972
Units: Participants	846	619	720	752

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2180	2178		
Units: Participants	580	602		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAEs .

End point title	Number of subjects with SAEs .[34]

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

Within the 30-day (Days 0-29) post-booster vaccination period

Notes:

[34] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2473	1827	2447	2472
Units: Participants	27	20	34	22

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1825	1837		
Units: Participants	19	19		

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:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

From Month 0 up to Booster (Month 20), from Month 0 up to study end and from Month 20 up to study end

End point values	GSK257049 - GSK257049 Group	GSK257049 - Menjugate Group	Comparator Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	51	54	48	
Units: Participants				
Any SAE(s), Month 0 - Month 20	43	39	36	
Any SAE(s), Month 0 - Study end	47	46	42	
Any SAE(s), Month 20 - Study end	19	19	16	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of low-weight (LW) subjects with serious adverse events (SAEs).

End point title	Number of low-weight (LW) subjects with serious adverse events (SAEs).

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity. Low-weight subjects were defined as subjects whose weight for age z-score (WAZ) was > -3 and ≤ -2.

End point type	Secondary

End point timeframe:

From Month 0 up to Month 20

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	695	221	364	126
Units: Participants	174	63	89	38

Statistical analyses

No statistical analyses for this end point

Secondary: Number of low-weight (LW) subjects with serious adverse events (SAEs)

End point title	Number of low-weight (LW) subjects with serious adverse

	events (SAEs)[35]

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity. Low-weight subjects were defined as subjects whose weight for age z-score (WAZ) was > -3 and ≤ -2.

End point type	Secondary

End point timeframe:

From Booster (Month 20) up to study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[35] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	297	195	277	304
Units: Participants	38	24	32	40

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	232	211		
Units: Participants	34	21		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of very low-weight (VLW) subjects with serious adverse events (SAEs)

End point title	Number of very low-weight (VLW) subjects with serious adverse events (SAEs)

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity. Very low-weight subjects were defined as subjects whose weight for age z-score (WAZ) was ≤ -3.

End point type	Secondary

End point timeframe:

From Month 0 up to Month 20

End point values	GSK257049 [5-17M] Group	GSK257049 [6-12W] Group	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	207	147	97	67
Units: Participants	55	48	28	17

Statistical analyses

No statistical analyses for this end point

Secondary: Number of very low-weight subjects with serious adverse events (SAEs)

End point title	Number of very low-weight subjects with serious adverse events (SAEs)[36]

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity. Very low-weight subjects were defined as subjects whose weight for age z-score (WAZ) was ≤ -3.

End point type	Secondary

End point timeframe:

From Booster (Month 20) up to study end (median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)]

Notes:

[36] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	60	68	48	50
Units: Participants	11	15	5	8

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	48	47		
Units: Participants	6	9		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with fatal outcomes, by gender

End point title	Number of subjects with fatal outcomes, by gender[37]

End point description:

Mortality was presented as overall mortality (up to Month 20 and up to study end), mortality due to severe malaria as per secondary case definition(SCD), cerebral malaria as per secondary case definition (SCD), meningitis, fatal all-cause traumas and fatal malaria. SCD= Plasmodium falciparum malaria > 5000 parasites/mcL and 1 or more markers of severe malaria (prostration, respiratory distress, Blantyre score ≤ 2, seizures 2 or more, hypoglycemia < 2.2 mmol/L, acidosis BE ≤ -10.0 mmol/L,lactate ≥ 5.0 mmol/L, anemia < 5.0 g/dL.

End point type	Secondary

End point timeframe:

From Month 0 up to study end (SE - median follow-up time of 48 months post-Dose 1 for 5-17 months age category and of 38 months post-Dose 1 for 6-12 weeks age category)

Notes:

[37] - 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: As per the study design, some results were presented for pooled study groups, included in the analysis subsets but accounting for 2 or more of the baseline groups.

End point values	VeroRab Comparator [5-17M] Group	Menjugate Comparator [6-12W] Group	GSK257049 - GSK257049 [5-17M] Group	GSK257049 - Menjugate [5-17M] Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	1503	1100	1509	1500
Units: Participants				
Overall Mortality (M0-M20), Females	14	13	27	20
Overall Mortality (M0-SE), Females	17	16	35	32
Overall Mortality (M0-M20), Males	19	21	19	8
Overall Mortality (M0-SE), Males	29	26	26	19
Severe Malaria SCD, All, Females	100	75	75	107
Severe Malaria SCD, All, Males	134	79	87	115
Severe Malaria SCD, Fatal, Females	2	0	4	4
Severe Malaria SCD, Fatal, Males	2	2	3	4
Cerebral Malaria SCD, All, Females	7	7	16	14
Cerebral Malaria SCD, All, Males	9	3	10	14
Cerebral Malaria SCD, Fatal, Females	2	0	3	4
Cerebral Malaria SCD, Fatal, Males	0	0	2	1
Meningitis, All, Females	1	3	5	5
Meningitis, All, Males	2	3	6	5
Meningitis, Fatal, Females	0	1	2	3
Meningitis, Fatal, Males	1	2	2	0
Fatal All-Cause Traumas, Females	1	2	3	4
Fatal All-Cause Traumas, Males	3	0	4	1
Fatal Malaria, Females	4	3	9	8
Fatal Malaria, Males	8	3	4	9

End point values	GSK257049 - GSK257049 [6-12W] Group	GSK257049 - Menjugate [6-12W] Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1116	1118		
Units: Participants				
Overall Mortality (M0-M20), Females	20	24		

Overall Mortality (M0-SE), Females	27	29		
Overall Mortality (M0-M20), Males	20	20		
Overall Mortality (M0-SE), Males	24	26		
Severe Malaria SCD, All, Females	57	49		
Severe Malaria SCD, All, Males	78	80		
Severe Malaria SCD, Fatal, Females	2	0		
Severe Malaria SCD, Fatal, Males	2	2		
Cerebral Malaria SCD, All, Females	1	5		
Cerebral Malaria SCD, All, Males	9	7		
Cerebral Malaria SCD, Fatal, Females	1	0		
Cerebral Malaria SCD, Fatal, Males	1	1		
Meningitis, All, Females	2	2		
Meningitis, All, Males	3	5		
Meningitis, Fatal, Females	0	0		
Meningitis, Fatal, Males	1	1		
Fatal All-Cause Traumas, Females	1	1		
Fatal All-Cause Traumas, Males	1	2		
Fatal Malaria, Females	5	4		
Fatal Malaria, Males	3	8		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local, general AEs: during 7-days (Days 0-6) post-vaccination periods; Unsolicited AEs: during 30-days (Days 0-29) post-vaccination periods; SAEs: from Day 0 up to study end (48 months for 5-17M subjects; 38 months for 6-12W subjects).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	GSK257049 [5-17M] Group

Reporting group description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine, according to a 0-1-2 Month schedule, followed by either a booster dose of the same GSK257049 vaccine or a dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Reporting group title	Menjugate Comparator [6-12W] Group

Reporting group description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of Menjugate® vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 12. All vaccines have been administered intramuscularly in the left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Reporting group title	VeroRab Comparator [5-17M] Group

Reporting group description:

Male or female children between and including 5 to 17 months of age [5-17M], who received a 3-dose primary vaccination course of the VeroRab® vaccine, according to a 0-1-2 Month schedule, followed by a booster dose of Menjugate® vaccine, at Month 20. Both vaccines have been administered intramuscularly into the left deltoid.

Reporting group title	GSK257049 [6-12W] Group

Reporting group description:

Male or female children between and including 6 to 12 weeks of age [6-12W], who received a 3-dose primary vaccination course of the GSK257049 malaria vaccine co-administered with Polio Sabin™ and Tritanrix HepB™/Hib vaccines, according to a 0-1-2 Month schedule, followed by either a booster dose of the GSK257049 and Polio Sabin™ vaccines or a booster dose of Menjugate® and Polio Sabin™ vaccines, at Month 20. All vaccines have been administered intramuscularly in the anterolateral left thigh (GSK257049 vaccine); left deltoid (GSK257049 booster dose); left thigh for children under 1 year and left deltoid for children above 1 year of age (Menjugate® vaccine); anterolateral right thigh (Tritanrix HepB™/Hib vaccine), except for the Polio Sabin™ vaccine, which has been given orally.

Serious adverse events	GSK257049 [5-17M] Group	Menjugate Comparator [6-12W] Group	VeroRab Comparator [5-17M] Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1475 / 5948 (24.80%)	622 / 2179 (28.55%)	848 / 2974 (28.51%)
number of deaths (all causes)	112	42	106
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute promyelocytic leukaemia			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Inflammatory pseudotumour			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Brain neoplasm			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Langerhans' cell histiocytosis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Shock			
subjects affected / exposed	3 / 5948 (0.05%)	4 / 2179 (0.18%)	5 / 2974 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			

subjects affected / exposed	4 / 5948 (0.07%)	3 / 2179 (0.14%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drowning			
subjects affected / exposed	5 / 5948 (0.08%)	1 / 2179 (0.05%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Hernia			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Hypothermia			
subjects affected / exposed	2 / 5948 (0.03%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Pyrexia			
subjects affected / exposed	28 / 5948 (0.47%)	18 / 2179 (0.83%)	16 / 2974 (0.54%)
occurrences causally related to treatment / all	0 / 28	0 / 18	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 5948 (0.00%)	2 / 2179 (0.09%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			

subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Hypersensitivity			
subjects affected / exposed	3 / 5948 (0.05%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune reconstitution inflammatory syndrome			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Social circumstances			
Child abuse			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Sexual abuse			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Apnoeic attack			

subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Asphyxia			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Asthma			
subjects affected / exposed	15 / 5948 (0.25%)	7 / 2179 (0.32%)	8 / 2974 (0.27%)
occurrences causally related to treatment / all	0 / 21	0 / 7	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Bronchospasm			
subjects affected / exposed	2 / 5948 (0.03%)	5 / 2179 (0.23%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Interstitial lung disease			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Pleural effusion			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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	8 / 5948 (0.13%)	4 / 2179 (0.18%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Pneumonitis			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Respiratory acidosis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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 arrest			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Psychiatric disorders			
Neurodevelopmental disorder			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental poisoning			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Arthropod sting			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chemical			
subjects affected / exposed	4 / 5948 (0.07%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns first degree			
subjects affected / exposed	4 / 5948 (0.07%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Burns second degree			
subjects affected / exposed	6 / 5948 (0.10%)	3 / 2179 (0.14%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical injury			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Chemical poisoning			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	7 / 2974 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Crush injury			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Disinfectant poisoning			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dislocation of vertebra			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Exposure to toxic agent			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Eye contusion			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Eye injury			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Femur fracture			
subjects affected / exposed	3 / 5948 (0.05%)	2 / 2179 (0.09%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	5 / 5948 (0.08%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body aspiration			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Fractured skull depressed			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Greenstick fracture			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Head injury			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herbal toxicity			

subjects affected / exposed	5 / 5948 (0.08%)	3 / 2179 (0.14%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human bite			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Laceration			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Penis injury			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Petroleum distillate poisoning			

subjects affected / exposed	4 / 5948 (0.07%)	1 / 2179 (0.05%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis chemical			
subjects affected / exposed	5 / 5948 (0.08%)	0 / 2179 (0.00%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary contusion			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatic nerve injury			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin injury			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Snake bite			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Soft tissue injury			

subjects affected / exposed	2 / 5948 (0.03%)	3 / 2179 (0.14%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	25 / 5948 (0.42%)	11 / 2179 (0.50%)	15 / 2974 (0.50%)
occurrences causally related to treatment / all	0 / 26	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaccination failure			
subjects affected / exposed	0 / 5948 (0.00%)	2 / 2179 (0.09%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Wrist fracture			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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			
Atrial septal defect			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral palsy			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Choledochal cyst			

subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital megacolon			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Fallot's tetralogy			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	2 / 5948 (0.03%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Phimosis			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia			
subjects affected / exposed	5 / 5948 (0.08%)	5 / 2179 (0.23%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis			

subjects affected / exposed	8 / 5948 (0.13%)	5 / 2179 (0.23%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 15	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trisomy 21			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Urethral valves			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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 / 5948 (0.00%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Cardiac failure			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Pericardial effusion			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Nervous system disorders			

Arachnoid cyst			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar ataxia			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Cerebral atrophy			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	102 / 5948 (1.71%)	32 / 2179 (1.47%)	58 / 2974 (1.95%)
occurrences causally related to treatment / all	0 / 122	0 / 45	0 / 64
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalomalacia			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Encephalopathy			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Epilepsy			
subjects affected / exposed	13 / 5948 (0.22%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	344 / 5948 (5.78%)	103 / 2179 (4.73%)	166 / 2974 (5.58%)
occurrences causally related to treatment / all	0 / 466	0 / 127	0 / 221
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Hemiparesis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Loss of consciousness			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Meningism			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Mental retardation			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Monoparesis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Paraparesis			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Uraemic encephalopathy			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Speech disorder developmental			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	277 / 5948 (4.66%)	116 / 2179 (5.32%)	198 / 2974 (6.66%)
occurrences causally related to treatment / all	0 / 329	0 / 138	0 / 246
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Haemolysis			

subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Haemolytic anaemia			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Hypochromic anaemia			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Intravascular haemolysis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemoid reaction			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	7 / 5948 (0.12%)	2 / 2179 (0.09%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Pancytopenia			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Hearing impaired			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Eye disorders			
Periorbital oedema			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Aphthous stomatitis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Colitis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Enteritis			
subjects affected / exposed	28 / 5948 (0.47%)	18 / 2179 (0.83%)	15 / 2974 (0.50%)
occurrences causally related to treatment / all	0 / 28	0 / 18	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 5948 (0.03%)	4 / 2179 (0.18%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Haematemesis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Ileus paralytic			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			

subjects affected / exposed	0 / 5948 (0.00%)	3 / 2179 (0.14%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Intestinal perforation			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Intussusception			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Rectal polyp			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Rectal prolapse			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress ulcer			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Umbilical hernia			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia, obstructive			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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 gastrointestinal haemorrhage			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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			
Cholecystitis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis toxic			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Drug eruption			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Erythema multiforme			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Rash			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Rash maculo-papular			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Rash papular			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Stevens-johnson syndrome			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitiligo			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Glomerulonephritis			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Glomerulonephritis acute			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Nephritis			

subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Hydronephrosis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Nephrotic syndrome			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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 tubular necrosis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Compartment syndrome			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Joint effusion			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Dactylitis			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Osteoarthritis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Myositis			
subjects affected / exposed	3 / 5948 (0.05%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torticollis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Rickets			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	14 / 5948 (0.24%)	5 / 2179 (0.23%)	5 / 2974 (0.17%)
occurrences causally related to treatment / all	0 / 14	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Abscess limb			

subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Acarodermatitis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Aids dementia complex			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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	9 / 5948 (0.15%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascariasis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Bacteraemia			

subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	1 / 5948 (0.02%)	2 / 2179 (0.09%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone tuberculosis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Breast abscess			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	38 / 5948 (0.64%)	24 / 2179 (1.10%)	18 / 2974 (0.61%)
occurrences causally related to treatment / all	0 / 42	0 / 26	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	28 / 5948 (0.47%)	3 / 2179 (0.14%)	21 / 2974 (0.71%)
occurrences causally related to treatment / all	0 / 31	0 / 3	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	68 / 5948 (1.14%)	34 / 2179 (1.56%)	40 / 2974 (1.34%)
occurrences causally related to treatment / all	0 / 76	0 / 36	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous impetigo			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Burkholderia cepacia complex sepsis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Burn infection			
subjects affected / exposed	3 / 5948 (0.05%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Cellulitis			
subjects affected / exposed	15 / 5948 (0.25%)	6 / 2179 (0.28%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 15	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis of male external genital organ			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis pharyngeal			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Central nervous system viral infection			

subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Cerebral malaria			
subjects affected / exposed	8 / 5948 (0.13%)	2 / 2179 (0.09%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholera			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Conjunctivitis			
subjects affected / exposed	6 / 5948 (0.10%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis infected			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			

subjects affected / exposed	24 / 5948 (0.40%)	7 / 2179 (0.32%)	9 / 2974 (0.30%)
occurrences causally related to treatment / all	0 / 24	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema infected			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Encephalitis			
subjects affected / exposed	5 / 5948 (0.08%)	1 / 2179 (0.05%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis viral			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Encephalomyelitis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Enterococcal sepsis			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Escherichia sepsis			

subjects affected / exposed	0 / 5948 (0.00%)	2 / 2179 (0.09%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 5948 (0.02%)	2 / 2179 (0.09%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Febrile infection			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Furuncle			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Gastroenteritis			
subjects affected / exposed	302 / 5948 (5.08%)	171 / 2179 (7.85%)	177 / 2974 (5.95%)
occurrences causally related to treatment / all	0 / 335	0 / 192	0 / 192
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis escherichia coli			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	5 / 5948 (0.08%)	4 / 2179 (0.18%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis shigella			

subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal candidiasis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Giardiasis			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingivitis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Groin abscess			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Haemophilus sepsis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Helminthic infection			
subjects affected / exposed	10 / 5948 (0.17%)	1 / 2179 (0.05%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 12	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis a			

subjects affected / exposed	4 / 5948 (0.07%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis b			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Hepatitis infectious			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Hiv associated nephropathy			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Hiv infection			
subjects affected / exposed	41 / 5948 (0.69%)	12 / 2179 (0.55%)	18 / 2974 (0.61%)
occurrences causally related to treatment / all	0 / 41	0 / 12	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiv infection who clinical stage ii			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiv infection who clinical stage iii			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Hiv infection who clinical stage iv			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Impetigo			

subjects affected / exposed	3 / 5948 (0.05%)	1 / 2179 (0.05%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Infection			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Injection site abscess			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Injection site cellulitis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Klebsiella sepsis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeria sepsis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Liver abscess			

subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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	11 / 5948 (0.18%)	7 / 2179 (0.32%)	7 / 2974 (0.24%)
occurrences causally related to treatment / all	0 / 11	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	5 / 5948 (0.08%)	2 / 2179 (0.09%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node abscess			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Lymph node tuberculosis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis bacterial			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	639 / 5948 (10.74%)	236 / 2179 (10.83%)	423 / 2974 (14.22%)
occurrences causally related to treatment / all	0 / 850	0 / 303	0 / 533
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			

subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	0 / 2974 (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
Measles			
subjects affected / exposed	9 / 5948 (0.15%)	8 / 2179 (0.37%)	5 / 2974 (0.17%)
occurrences causally related to treatment / all	0 / 9	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	10 / 5948 (0.17%)	3 / 2179 (0.14%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 10	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis haemophilus			
subjects affected / exposed	3 / 5948 (0.05%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis meningococcal			
subjects affected / exposed	5 / 5948 (0.08%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	1 / 5948 (0.02%)	2 / 2179 (0.09%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis salmonella			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Meningitis tuberculous			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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 viral			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Moraxella infection			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Mumps			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Mycobacterium ulcerans infection			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Oral candidiasis			
subjects affected / exposed	10 / 5948 (0.17%)	1 / 2179 (0.05%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 10	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal candidiasis			
subjects affected / exposed	2 / 5948 (0.03%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	5 / 5948 (0.08%)	2 / 2179 (0.09%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Otitis media			
subjects affected / exposed	29 / 5948 (0.49%)	7 / 2179 (0.32%)	22 / 2974 (0.74%)
occurrences causally related to treatment / all	0 / 29	0 / 7	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	4 / 5948 (0.07%)	1 / 2179 (0.05%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Parotitis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal abscess			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Periorbital cellulitis			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Pharyngitis			

subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmodium ovale infection			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal bacteraemia			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Pneumococcal sepsis			
subjects affected / exposed	9 / 5948 (0.15%)	3 / 2179 (0.14%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	417 / 5948 (7.01%)	202 / 2179 (9.27%)	223 / 2974 (7.50%)
occurrences causally related to treatment / all	0 / 532	0 / 286	0 / 287
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia streptococcal			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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 viral			

subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Postoperative wound infection			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Pseudomonal sepsis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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	8 / 5948 (0.13%)	2 / 2179 (0.09%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 9	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyomyositis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rabies			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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 tract infection			

subjects affected / exposed	4 / 5948 (0.07%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rubella			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Salmonella bacteraemia			
subjects affected / exposed	0 / 5948 (0.00%)	1 / 2179 (0.05%)	0 / 2974 (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
Salmonella sepsis			
subjects affected / exposed	70 / 5948 (1.18%)	37 / 2179 (1.70%)	42 / 2974 (1.41%)
occurrences causally related to treatment / all	0 / 73	0 / 40	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	4 / 5948 (0.07%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schistosomiasis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	60 / 5948 (1.01%)	13 / 2179 (0.60%)	43 / 2974 (1.45%)
occurrences causally related to treatment / all	0 / 61	0 / 15	0 / 46
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Shigella infection			

subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	3 / 5948 (0.05%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	9 / 5948 (0.15%)	2 / 2179 (0.09%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 10	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed	3 / 5948 (0.05%)	1 / 2179 (0.05%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Streptococcal sepsis			
subjects affected / exposed	2 / 5948 (0.03%)	2 / 2179 (0.09%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	9 / 5948 (0.15%)	3 / 2179 (0.14%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			

subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Taeniasis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Tinea capitis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic shock syndrome			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Tracheobronchitis			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Trichiniasis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	9 / 5948 (0.15%)	3 / 2179 (0.14%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 9	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			

subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	68 / 5948 (1.14%)	24 / 2179 (1.10%)	43 / 2974 (1.45%)
occurrences causally related to treatment / all	0 / 74	0 / 24	0 / 45
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	45 / 5948 (0.76%)	22 / 2179 (1.01%)	28 / 2974 (0.94%)
occurrences causally related to treatment / all	0 / 47	0 / 23	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (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
Urosepsis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal infection			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Varicella			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound sepsis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Hypoglycaemia			
subjects affected / exposed	20 / 5948 (0.34%)	3 / 2179 (0.14%)	18 / 2974 (0.61%)
occurrences causally related to treatment / all	0 / 21	0 / 3	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 5948 (0.02%)	1 / 2179 (0.05%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoproteinaemia			

subjects affected / exposed	2 / 5948 (0.03%)	0 / 2179 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kwashiorkor			
subjects affected / exposed	15 / 5948 (0.25%)	4 / 2179 (0.18%)	17 / 2974 (0.57%)
occurrences causally related to treatment / all	0 / 18	0 / 4	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	54 / 5948 (0.91%)	19 / 2179 (0.87%)	21 / 2974 (0.71%)
occurrences causally related to treatment / all	0 / 58	0 / 21	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Marasmus			
subjects affected / exposed	14 / 5948 (0.24%)	7 / 2179 (0.32%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 14	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 5948 (0.00%)	0 / 2179 (0.00%)	0 / 2974 (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
Underweight			
subjects affected / exposed	1 / 5948 (0.02%)	0 / 2179 (0.00%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK257049 [6-12W] Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	1186 / 4358 (27.21%)		
number of deaths (all causes)	46		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute promyelocytic leukaemia			

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inflammatory pseudotumour			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain neoplasm			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Langerhans' cell histiocytosis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		

Drowning			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Generalised oedema			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hernia			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypothermia			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Injection site reaction			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	27 / 4358 (0.62%)		
occurrences causally related to treatment / all	0 / 27		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaphylactic reaction			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity			

subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Immune reconstitution inflammatory syndrome				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Social circumstances				
Child abuse				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sexual abuse				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Acquired phimosis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Apnoeic attack				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asphyxia				

subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspiration				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	9 / 4358 (0.21%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Bronchial hyperreactivity				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	8 / 4358 (0.18%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Interstitial lung disease				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructive airways disorder				

subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	4 / 4358 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory acidosis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory arrest				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory disorder				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Neurodevelopmental disorder				

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental poisoning			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Animal bite			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthropod sting			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis chemical			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burns first degree			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Burns second degree			
subjects affected / exposed	5 / 4358 (0.11%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Chemical injury			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chemical poisoning			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Crush injury			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disinfectant poisoning			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dislocation of vertebra			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Exposure to toxic agent			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye contusion			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye injury			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	4 / 4358 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Foreign body			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body aspiration			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fractured skull depressed			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Greenstick fracture			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	4 / 4358 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Herbal toxicity			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Human bite			

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laceration			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb injury			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Limb traumatic amputation			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penis injury			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Petroleum distillate poisoning			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonitis chemical			

subjects affected / exposed	4 / 4358 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Poisoning				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary contusion				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sciatic nerve injury				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin injury				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Snake bite				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue injury				
subjects affected / exposed	2 / 4358 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Thermal burn				

subjects affected / exposed	24 / 4358 (0.55%)			
occurrences causally related to treatment / all	0 / 24			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vaccination failure				
subjects affected / exposed	2 / 4358 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Wound				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Atrial septal defect				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral palsy				
subjects affected / exposed	2 / 4358 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Choledochal cyst				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital megacolon				

subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cryptorchism				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fallot's tetralogy				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Glucose-6-phosphate dehydrogenase deficiency				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrocele				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Phimosis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sickle cell anaemia				
subjects affected / exposed	4 / 4358 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Sickle cell anaemia with crisis				
subjects affected / exposed	5 / 4358 (0.11%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Trisomy 21				

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urethral valves			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular septal defect			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Arachnoid cyst			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebellar ataxia			

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral atrophy			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion			
subjects affected / exposed	78 / 4358 (1.79%)		
occurrences causally related to treatment / all	0 / 98		
deaths causally related to treatment / all	0 / 0		
Depressed level of consciousness			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalomalacia			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalopathy			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion			
subjects affected / exposed	191 / 4358 (4.38%)		
occurrences causally related to treatment / all	0 / 248		
deaths causally related to treatment / all	0 / 0		
Haemorrhage intracranial			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hemiplegia			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningism			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic encephalopathy			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mental retardation			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Monoparesis			

subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paraparesis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myoclonus				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uraemic encephalopathy				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Speech disorder developmental				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	198 / 4358 (4.54%)			
occurrences causally related to treatment / all	0 / 258			
deaths causally related to treatment / all	0 / 0			
Disseminated intravascular coagulation				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolysis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolytic anaemia				

subjects affected / exposed	2 / 4358 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypochromic anaemia				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intravascular haemolysis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukaemoid reaction				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphadenitis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Deafness				

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hearing impaired			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Periorbital oedema			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aphthous stomatitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	17 / 4358 (0.39%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 0		
Food poisoning			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus paralytic			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia, obstructive			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mouth ulceration			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal polyp			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal prolapse			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stomatitis			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Stress ulcer			

subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia, obstructive				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	2 / 4358 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis				
subjects affected / exposed	2 / 4358 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hepatitis acute				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis toxic				

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis allergic			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis exfoliative			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug eruption			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erythema multiforme			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash papular			

subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stevens-johnson syndrome				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin lesion				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urticaria				
subjects affected / exposed	2 / 4358 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Vitiligo				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Glomerulonephritis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glomerulonephritis acute				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nephritis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hydronephrosis				

subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nephrotic syndrome				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure acute				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal tubular necrosis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthritis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Compartment syndrome				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Joint effusion				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dactylitis				

subjects affected / exposed	2 / 4358 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myositis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Torticollis				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rickets				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess				
subjects affected / exposed	12 / 4358 (0.28%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Abscess jaw				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess neck				

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acarodermatitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aids dementia complex			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amoebiasis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	6 / 4358 (0.14%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Ascariasis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone tuberculosis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain abscess			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast abscess			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	32 / 4358 (0.73%)		
occurrences causally related to treatment / all	0 / 33		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	17 / 4358 (0.39%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	54 / 4358 (1.24%)		
occurrences causally related to treatment / all	0 / 60		
deaths causally related to treatment / all	0 / 0		
Bullous impetigo			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Burkholderia cepacia complex sepsis			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burn infection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Candida infection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	10 / 4358 (0.23%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis orbital			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis pharyngeal			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Central nervous system viral infection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral malaria			

subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cholera			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Conjunctivitis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Conjunctivitis bacterial			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Croup infectious			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis infected			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disseminated tuberculosis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysentery			
subjects affected / exposed	10 / 4358 (0.23%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Eczema infected			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Empyema			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalitis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalitis viral			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalomyelitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterococcal sepsis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection			

subjects affected / exposed	3 / 4358 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Exanthema subitum				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile infection				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Furuncle				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	333 / 4358 (7.64%)			
occurrences causally related to treatment / all	0 / 379			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis escherichia coli				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis salmonella				
subjects affected / exposed	7 / 4358 (0.16%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis shigella				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal candidiasis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Giardiasis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gingivitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Groin abscess			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemophilus sepsis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Helminthic infection			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hepatitis a			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis b			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis infectious			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiv associated nephropathy			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiv infection			
subjects affected / exposed	36 / 4358 (0.83%)		
occurrences causally related to treatment / all	0 / 36		
deaths causally related to treatment / all	0 / 0		
Hiv infection who clinical stage ii			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiv infection who clinical stage iii			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hiv infection who clinical stage iv			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Impetigo			
subjects affected / exposed	4 / 4358 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Infected skin ulcer			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injection site abscess			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injection site cellulitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Klebsiella sepsis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Listeria sepsis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver abscess			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lobar pneumonia			

subjects affected / exposed	17 / 4358 (0.39%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	4 / 4358 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Ludwig angina			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymph node abscess			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymph node tuberculosis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis bacterial			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaria			
subjects affected / exposed	392 / 4358 (8.99%)		
occurrences causally related to treatment / all	0 / 525		
deaths causally related to treatment / all	0 / 0		
Mastoiditis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Measles			

subjects affected / exposed	24 / 4358 (0.55%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 0		
Meningitis			
subjects affected / exposed	5 / 4358 (0.11%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Meningitis haemophilus			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis meningococcal			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis pneumococcal			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Meningitis salmonella			
subjects affected / exposed	4 / 4358 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Meningitis tuberculous			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis viral			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Moraxella infection			

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mumps			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mycobacterium ulcerans infection			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral candidiasis			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Otitis externa			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis media			

subjects affected / exposed	22 / 4358 (0.50%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 0		
Otitis media acute			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Otitis media chronic			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parotitis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Perineal abscess			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital cellulitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasmodium ovale infection			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumococcal bacteraemia			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumococcal sepsis			
subjects affected / exposed	9 / 4358 (0.21%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	5 / 4358 (0.11%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	424 / 4358 (9.73%)		
occurrences causally related to treatment / all	0 / 547		
deaths causally related to treatment / all	0 / 0		
Pneumonia pneumococcal			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia streptococcal			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pseudomonal sepsis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			
subjects affected / exposed	12 / 4358 (0.28%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyoderma			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyomyositis			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Rabies			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rubella			

subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Salmonella bacteraemia			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Salmonella sepsis			
subjects affected / exposed	60 / 4358 (1.38%)		
occurrences causally related to treatment / all	0 / 63		
deaths causally related to treatment / all	0 / 0		
Salmonellosis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schistosomiasis			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	38 / 4358 (0.87%)		
occurrences causally related to treatment / all	0 / 38		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Shigella infection			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin bacterial infection			

subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis			
subjects affected / exposed	10 / 4358 (0.23%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Staphylococcal skin infection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Streptococcal infection			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Streptococcal sepsis			
subjects affected / exposed	2 / 4358 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	7 / 4358 (0.16%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Superinfection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Taeniasis			

subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tinea capitis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	3 / 4358 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Toxic shock syndrome				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheobronchitis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Trichiniasis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tuberculosis				
subjects affected / exposed	6 / 4358 (0.14%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Typhoid fever				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				

subjects affected / exposed	50 / 4358 (1.15%)		
occurrences causally related to treatment / all	0 / 52		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	26 / 4358 (0.60%)		
occurrences causally related to treatment / all	0 / 28		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection bacterial			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vaginal infection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicella			
subjects affected / exposed	3 / 4358 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection			

subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound sepsis				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
subjects affected / exposed	1 / 4358 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				
subjects affected / exposed	6 / 4358 (0.14%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoproteinaemia				
subjects affected / exposed	0 / 4358 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Kwashiorkor				

subjects affected / exposed	16 / 4358 (0.37%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	50 / 4358 (1.15%)		
occurrences causally related to treatment / all	0 / 58		
deaths causally related to treatment / all	0 / 0		
Marasmus			
subjects affected / exposed	11 / 4358 (0.25%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	1 / 4358 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Underweight			
subjects affected / exposed	0 / 4358 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	GSK257049 [5-17M] Group	Menjugate Comparator [6-12W] Group	VeroRab Comparator [5-17M] Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1410 / 5948 (23.71%)	691 / 2179 (31.71%)	664 / 2974 (22.33%)
Nervous system disorders			
Somnolence			
subjects affected / exposed[1]	272 / 1479 (18.39%)	131 / 738 (17.75%)	87 / 721 (12.07%)
occurrences (all)	364	179	115
General disorders and administration site conditions			
Pain			
subjects affected / exposed[2]	493 / 1479 (33.33%)	348 / 738 (47.15%)	132 / 721 (18.31%)
occurrences (all)	688	571	165

Pyrexia			
subjects affected / exposed[3]	1028 / 1479 (69.51%)	408 / 738 (55.28%)	306 / 721 (42.44%)
occurrences (all)	1971	660	416
Swelling			
subjects affected / exposed[4]	352 / 1479 (23.80%)	272 / 738 (36.86%)	138 / 721 (19.14%)
occurrences (all)	491	407	192
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed[5]	196 / 1479 (13.25%)	0 / 738 (0.00%)	92 / 721 (12.76%)
occurrences (all)	226	0	107
Enteritis			
subjects affected / exposed[6]	136 / 1479 (9.20%)	80 / 738 (10.84%)	65 / 721 (9.02%)
occurrences (all)	148	97	74
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed[7]	119 / 1479 (8.05%)	0 / 738 (0.00%)	47 / 721 (6.52%)
occurrences (all)	126	0	54
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed[8]	147 / 1479 (9.94%)	172 / 738 (23.31%)	57 / 721 (7.91%)
occurrences (all)	162	254	66
Psychiatric disorders			
Irritability			
subjects affected / exposed[9]	412 / 1479 (27.86%)	255 / 738 (34.55%)	106 / 721 (14.70%)
occurrences (all)	583	411	131
Infections and infestations			
Bronchitis			
subjects affected / exposed[10]	83 / 1479 (5.61%)	33 / 738 (4.47%)	37 / 721 (5.13%)
occurrences (all)	92	36	41
Conjunctivitis			
subjects affected / exposed[11]	126 / 1479 (8.52%)	81 / 738 (10.98%)	74 / 721 (10.26%)
occurrences (all)	135	87	77
Gastroenteritis			
subjects affected / exposed[12]	368 / 1479 (24.88%)	150 / 738 (20.33%)	159 / 721 (22.05%)
occurrences (all)	435	207	188
Malaria			

subjects affected / exposed[13]	305 / 1479 (20.62%)	108 / 738 (14.63%)	207 / 721 (28.71%)
occurrences (all)	422	141	289
Otitis media			
subjects affected / exposed[14]	0 / 1479 (0.00%)	41 / 738 (5.56%)	0 / 721 (0.00%)
occurrences (all)	0	42	0
Pneumonia			
subjects affected / exposed[15]	175 / 1479 (11.83%)	33 / 738 (4.47%)	72 / 721 (9.99%)
occurrences (all)	200	36	84
Rhinitis			
subjects affected / exposed[16]	123 / 1479 (8.32%)	94 / 738 (12.74%)	52 / 721 (7.21%)
occurrences (all)	139	109	59
Upper respiratory tract infection			
subjects affected / exposed[17]	683 / 1479 (46.18%)	344 / 738 (46.61%)	343 / 721 (47.57%)
occurrences (all)	1006	503	493
Viral upper respiratory tract infection			
subjects affected / exposed[18]	111 / 1479 (7.51%)	49 / 738 (6.64%)	60 / 721 (8.32%)
occurrences (all)	126	55	69
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed[19]	444 / 1479 (30.02%)	114 / 738 (15.45%)	151 / 721 (20.94%)
occurrences (all)	609	158	190

Non-serious adverse events	GSK257049 [6-12W] Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1360 / 4358 (31.21%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed[1]	302 / 1462 (20.66%)		
occurrences (all)	475		
General disorders and administration site conditions			
Pain			
subjects affected / exposed[2]	729 / 1462 (49.86%)		
occurrences (all)	1251		
Pyrexia			

subjects affected / exposed[3]	966 / 1462 (66.07%)		
occurrences (all)	1852		
Swelling			
subjects affected / exposed[4]	456 / 1462 (31.19%)		
occurrences (all)	713		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed[5]	0 / 1462 (0.00%)		
occurrences (all)	0		
Enteritis			
subjects affected / exposed[6]	149 / 1462 (10.19%)		
occurrences (all)	195		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed[7]	0 / 1462 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed[8]	307 / 1462 (21.00%)		
occurrences (all)	436		
Psychiatric disorders			
Irritability			
subjects affected / exposed[9]	589 / 1462 (40.29%)		
occurrences (all)	1017		
Infections and infestations			
Bronchitis			
subjects affected / exposed[10]	69 / 1462 (4.72%)		
occurrences (all)	80		
Conjunctivitis			
subjects affected / exposed[11]	139 / 1462 (9.51%)		
occurrences (all)	147		
Gastroenteritis			
subjects affected / exposed[12]	257 / 1462 (17.58%)		
occurrences (all)	339		
Malaria			

subjects affected / exposed[13]	199 / 1462 (13.61%)		
occurrences (all)	249		
Otitis media			
subjects affected / exposed[14]	73 / 1462 (4.99%)		
occurrences (all)	82		
Pneumonia			
subjects affected / exposed[15]	87 / 1462 (5.95%)		
occurrences (all)	94		
Rhinitis			
subjects affected / exposed[16]	166 / 1462 (11.35%)		
occurrences (all)	183		
Upper respiratory tract infection			
subjects affected / exposed[17]	655 / 1462 (44.80%)		
occurrences (all)	1014		
Viral upper respiratory tract infection			
subjects affected / exposed[18]	90 / 1462 (6.16%)		
occurrences (all)	111		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed[19]	281 / 1462 (19.22%)		
occurrences (all)	412		

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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[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.
Justification: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[3] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[4] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[5] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[6] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[7] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[8] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[9] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[10] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[11] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[12] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[13] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[14] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[15] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[16] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[17] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[18] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

[19] - 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: Solicited general events were only reported for subjects that has a symptom sheet filled-in.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

Due to limitations in terms of record format and available reports, placeholder values were presented for the analysis sets' baseline characteristics.

Notes: