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	v2
This version publication date	06 April 2016
First version publication date	01 August 2015
Version creation reason	• New data added to full data set Data for secondary endpoints have been added.

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 Biologicals
Sponsor organisation address	GlaxoSmithKline Biologicals, Rue de l'Institut 89, Rixensart, B-1330, Belgium, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, 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 whose age at first dose will be from 6-12 weeks and will receive vaccine in co-administration with DTPwHepB/Hib antigens (Tritanrix HepB/Hib) and OPV. Duration of follow up will be 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 whose age at first dose will be from 5-17 months. Duration of follow up will be 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	Ghana: 2621
Country: Number of subjects enrolled	Tanzania, United Republic of: 3210
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 [M] 0-3) and a booster (BST) phase at M20, each followed by a related PRI/BST efficacy, immunogenicity and safety (EIS) follow-up (FU) phase, and an EIS extension, from M32 to the median M48 time point for 5-17M subjects & the median M38 time point for 6-12W subjects.

Pre-assignment

Screening details:

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

Pre-assignment period milestones

Number of subjects started	15459
Number of subjects completed	15459

Period 1

Period 1 title	Entire Study Period (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	R3R (5-17M) Group

Arm description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) according to a Month 0, 1 and 2 followed by a booster dose of the same RTS,S/AS01 vaccine administered at Month 20. The RTS,S/AS01 vaccine was administered intramuscularly in the left deltoid.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S, GSK 257049, RTS,S/AS01
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 primary doses according to a Month 0, 1 and 2 followed by a booster dose at Month 20.

Arm title	R3C (5-17M) Group

Arm description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) according to a Month 0, 1 and 2 followed by a booster dose of Menjugate (or MenC vaccine) administered at Month 20. The RTS,S/AS01 and MenC vaccines were administered intramuscularly in the left deltoid.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S, GSK 257049, RTS,S/AS01
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details: 3 primary doses according to a Month 0, 1 and 2	
Investigational medicinal product name	MENJUGATE KIT
Investigational medicinal product code	
Other name	Menjugate, MenC
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: One dose at Month 20	
Arm title	C3C (5-17M) Group

Arm description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of Verorab (also referred to as Rabies vaccine) according to a Month 0, 1 and 2 followed by a booster dose of the Menjugate vaccine (MenC) administered at Month 20. The Rabies and MenC vaccines were administered intramuscularly in the left deltoid.

Arm type	Active comparator
Investigational medicinal product name	Verorab
Investigational medicinal product code	
Other name	Rabies
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 3-dose primary vaccination course according to a Month 0, 1 and 2	
Investigational medicinal product name	MENJUGATE KIT
Investigational medicinal product code	
Other name	Menjugate, MenC
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: One dose at Month 20	
Arm title	R3R (6-12W) Group

Arm description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of the same RTS,S/AS01 vaccine co-administered with OPV at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the primary RTS,S/AS01 vaccine doses were injected in the anterolateral left thigh and the booster dose into the left deltoid; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S, GSK 257049, RTS,S/AS01
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 3 primary doses according to a Month 0, 1 and 2 followed by a booster dose at Month 20.	
Investigational medicinal product name	Tritanrix-HepB
Investigational medicinal product code	DTPw-HBV
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses in the anterolateral right thigh according to a Month 0, 1 and 2 of Tritanrix-HepB (DTPw-HBV /Hib) reconstituted into Tritanrix HepB/Hib by combining with Hiberix (Hib) vaccine

Investigational medicinal product name	Hiberix
Investigational medicinal product code	Hib
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses in the anterolateral right thigh according to a Month 0, 1 and 2 as part of 3 dose of Tritanrix-HepB (DTPw-HBV /Hib) reconstituted into Tritanrix HepB/Hib by combining with Hiberix (Hib) vaccine

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

Dosage and administration details:

3 primary doses according to a Month 0, 1 and 2 followed by a booster dose at Month 20.

Arm title	R3C (6-12W) Group

Arm description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of dose of Menjugate (or MenC vaccine) co-administered with OPV vaccine at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the primary RTS,S/AS01 vaccine doses were injected in the anterolateral left thigh; the MenC vaccine was injected in the left thigh for children < 1 year of age and into the left deltoid in children > 1 year of age; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S, GSK 257049, RTS,S/AS01
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 primary doses according to a Month 0, 1 and 2

Investigational medicinal product name	MENJUGATE KIT
Investigational medicinal product code	
Other name	Menjugate, MenC
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose at Month 20

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

Dosage and administration details:

3 doses in the anterolateral right thigh according to a Month 0, 1 and 2 of Tritanrix-HepB (DTPw-HBV /Hib) reconstituted into Tritanrix HepB/Hib by combining with Hiberix (Hib) vaccine

Investigational medicinal product name	Hiberix
Investigational medicinal product code	Hib
Other name	

Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses in the anterolateral right thigh according to a Month 0, 1 and 2 as part of 3 dose of Tritanrix-HepB (DTPw-HBV /Hib) reconstituted into Tritanrix HepB/Hib by combining with Hiberix (Hib) vaccine

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

Dosage and administration details:

3 primary doses according to a Month 0, 1 and 2 followed by a booster dose at Month 20.

Arm title	C3C (6-12W) Group

Arm description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of Menjugate (or MenC vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of dose of MenC vaccine co-administered with OPV vaccine at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the MenC vaccine was injected in the left thigh for children < 1 year of age and into the left deltoid in children > 1 year of age; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Arm type	Active comparator
Investigational medicinal product name	MENJUGATE KIT
Investigational medicinal product code	
Other name	Menjugate, MenC
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 primary doses according to a Month 0, 1 and 2 followed by a booster dose at Month 20.

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

Dosage and administration details:

3 doses in the anterolateral right thigh according to a Month 0, 1 and 2 of Tritanrix-HepB (DTPw-HBV /Hib) reconstituted into Tritanrix HepB/Hib by combining with Hiberix (Hib) vaccine

Investigational medicinal product name	Hiberix
Investigational medicinal product code	Hib
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses in the anterolateral right thigh according to a Month 0, 1 and 2 as part of 3 dose of Tritanrix-HepB (DTPw-HBV /Hib) reconstituted into Tritanrix HepB/Hib by combining with Hiberix (Hib) vaccine

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

Dosage and administration details:

3 primary doses according to a Month 0, 1 and 2 followed by a booster dose at Month 20.

Number of subjects in period 1	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group
Started	2976	2972	2974
Completed	2064	2038	2085
Not completed	912	934	889
Consent withdrawn by subject	297	290	272
Adverse event, non-fatal	61	51	47
Lost to follow-up	552	593	568
Protocol deviation	2	-	2

Number of subjects in period 1	R3R (6-12W) Group	R3C (6-12W) Group	C3C (6-12W) Group
Started	2180	2178	2179
Completed	1555	1533	1549
Not completed	625	645	630
Consent withdrawn by subject	157	138	144
Adverse event, non-fatal	51	55	44
Lost to follow-up	395	435	425
Protocol deviation	22	17	17

Baseline characteristics

Reporting groups

Reporting group title	R3R (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) according to a Month 0, 1 and 2 followed by a booster dose of the same RTS,S/AS01 vaccine administered at Month 20. The RTS,S/AS01 vaccine was administered intramuscularly in the left deltoid.

Reporting group title	R3C (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) according to a Month 0, 1 and 2 followed by a booster dose of Menjugate (or MenC vaccine) administered at Month 20. The RTS,S/AS01 and MenC vaccines were administered intramuscularly in the left deltoid.

Reporting group title	C3C (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of Verorab (also referred to as Rabies vaccine) according to a Month 0, 1 and 2 followed by a booster dose of the Menjugate vaccine (MenC) administered at Month 20. The Rabies and MenC vaccines were administered intramuscularly in the left deltoid.

Reporting group title	R3R (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of the same RTS,S/AS01 vaccine co-administered with OPV at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the primary RTS,S/AS01 vaccine doses were injected in the anterolateral left thigh and the booster dose into the left deltoid; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Reporting group title	R3C (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of dose of Menjugate (or MenC vaccine) co-administered with OPV vaccine at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the primary RTS,S/AS01 vaccine doses were injected in the anterolateral left thigh; the MenC vaccine was injected in the left thigh for children < 1 year of age and into the left deltoid in children > 1 year of age; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Reporting group title	C3C (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of Menjugate (or MenC vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of dose of MenC vaccine co-administered with OPV vaccine at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the MenC vaccine was injected in the left thigh for children < 1 year of age and into the left deltoid in children > 1 year of age; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Reporting group values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group
Number of subjects	2976	2972	2974

Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	2976	2972	2974
Age continuous Units: months			
arithmetic mean	10.7	10.6	10.6
standard deviation	± 3.79	± 3.82	± 3.75
Gender categorical Units: Subjects			
Female	1467	1500	1503
Male	1509	1472	1471

Reporting group values	R3R (6-12W) Group	R3C (6-12W) Group	C3C (6-12W) Group
Number of subjects	2180	2178	2179
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	2180	2178	2179
Age continuous Units: months			
arithmetic mean	7.2	7.1	7.1
standard deviation	± 1.45	± 1.39	± 1.43
Gender categorical Units: Subjects			
Female	1064	1060	1100
Male	1116	1118	1079

Reporting group values	Total		
Number of subjects	15459		
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	15459		
Age continuous Units: months			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	7694		
Male	7765		

End points reporting groups

Reporting group title	R3R (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) according to a Month 0, 1 and 2 followed by a booster dose of the same RTS,S/AS01 vaccine administered at Month 20. The RTS,S/AS01 vaccine was administered intramuscularly in the left deltoid.

Reporting group title	R3C (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) according to a Month 0, 1 and 2 followed by a booster dose of Menjugate (or MenC vaccine) administered at Month 20. The RTS,S/AS01 and MenC vaccines were administered intramuscularly in the left deltoid.

Reporting group title	C3C (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of Verorab (also referred to as Rabies vaccine) according to a Month 0, 1 and 2 followed by a booster dose of the Menjugate vaccine (MenC) administered at Month 20. The Rabies and MenC vaccines were administered intramuscularly in the left deltoid.

Reporting group title	R3R (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of the same RTS,S/AS01 vaccine co-administered with OPV at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the primary RTS,S/AS01 vaccine doses were injected in the anterolateral left thigh and the booster dose into the left deltoid; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Reporting group title	R3C (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of dose of Menjugate (or MenC vaccine) co-administered with OPV vaccine at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the primary RTS,S/AS01 vaccine doses were injected in the anterolateral left thigh; the MenC vaccine was injected in the left thigh for children < 1 year of age and into the left deltoid in children > 1 year of age; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Reporting group title	C3C (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of Menjugate (or MenC vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of dose of MenC vaccine co-administered with OPV vaccine at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the MenC vaccine was injected in the left thigh for children < 1 year of age and into the left deltoid in children > 1 year of age; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Subject analysis set title	RTS,S/AS01 (5-17M)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group results from the pooling of the R3R (5-17M) and R3C (5-17M) groups and include subjects who received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049) according to a Month 0, 1 and 2 schedule followed by, at Month 20, either a booster dose of the RTS,S/AS01 vaccine or a dose of Menjugate (or MenC). Refer to the respective descriptions for the R3R (5-17M) and R3C (5-17M) groups for details on routes of vaccination.

Subject analysis set title	RTS,S/AS01 (6-12W) Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group results from the pooling of the R3R (6-12W) and R3C (6-12W) groups and include subjects who received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049) co-administered with Polio Sabin (or OPV) and Tritanrix HepB/Hib (or DTPwHepB/Hib) according to a Month 0, 1 and 2 schedule followed by, at Month 20, either a booster dose of the RTS,S/AS01 and OPV vaccines or a booster dose of Menjugate (or MenC) and OPV vaccines. Refer to the respective descriptions for the R3R (6-12W) and R3C (6-12W) groups for details on routes of vaccination

Subject analysis set title	RTS,S/AS01 Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group results from the pooling of the R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups. Subjects aged 5 to 17 months at first vaccination received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049 vaccine) according to a Month 0, 1 and 2 schedule, followed by, at Month 20, either a booster dose of the RTS,S/AS01 vaccine or a dose of Menjugate (or MenC). Subjects aged 6 to 12 weeks at first vaccination received a 3-dose primary vaccination course of RTS,S/AS01 vaccine co-administered with Polio Sabin (or OPV) and Tritanrix HepB/Hib (or DTPwHepB/Hib) according to a Month 0, 1 and 2 schedule followed by, at Month 20, either a booster dose of RTS,S/AS01 and OPV vaccines or a booster dose of Menjugate (or MenC) and OPV vaccines. Refer to the respective descriptions for the R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups for details on routes of vaccination.

Subject analysis set title	R3R Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group results from the pooling of the R3R (5-17M) and R3R (6-12W) groups and include subjects who received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049) according to a Month 0, 1 and 2 schedule, followed by, at Month 20, either a booster dose of the RTS,S/AS01 vaccine. Refer to the respective descriptions for the R3R (5-17M) and R3R (6-12W) groups for details on other vaccines administered depending on age of subjects and routes of vaccination.

Subject analysis set title	R3C Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group results from the pooling of the R3C (5-17M) and R3C (6-12W) groups and include subjects who received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049) according to a Month 0, 1 and 2 schedule, followed by, at Month 20, either a booster dose of Menjugate (or MenC). Refer to the respective descriptions for the R3C (5-17M) and R3C (6-12W) groups for details on other vaccines administered depending on age of subjects and routes of vaccination.

Subject analysis set title	C3C Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group results from the pooling of the C3C (5-17M) and C3C (6-12W) groups and include subjects who received a 3-dose primary vaccination course of either Verorab (also referred to as Rabies vaccine (subjects aged 5-17 months at first vaccination) or Menjugate (or MenC) (subjects aged 6-12 weeks at first vaccination according to a Month 0, 1 and 2 schedule, followed by, at Month 20, either a booster dose of the MenC vaccine. Refer to the respective descriptions for the C3C (5-17M) and C3C (6-12W) groups for details on other vaccines administered depending on age of subjects and routes of vaccination.

Primary: Time to first or only clinical episode of Plasmodium falciparum (P. falciparum) malaria infection (CPFMI), or clinical malaria episode, of Primary Case Definition (CPFMI-PCD) - In subjects enrolled aged 5-17 months

End point title	Time to first or only clinical episode of Plasmodium falciparum (P. falciparum) malaria infection (CPFMI), or clinical malaria episode, of Primary Case Definition (CPFMI-PCD) - In subjects enrolled aged 5-17 months[1]

End point description:

A CPFMI-PCD was defined as an episode of malaria for which P. falciparum asexual parasitemia > 5000 parasites/µL accompanied by 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, the number of CPFMI events reported (n) over the period elapsed until the CPFMI event occurred for each group (T in year = sum of follow-up period expressed in years censored at the first occurrence of event in each group). 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	C3C (5-17M) Group	RTS,S/AS01 (5-17M)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1466	2830		
Units: n/T				
number (not applicable)				
RfoCPFMI-PCD 5-17M M2.5-14	0.833	0.435		

Statistical analyses

Statistical analysis title	Vaccine efficacy (VE) RTS,S/AS01 vs control

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 RTS,S/AS01 (5-17M) Group (HR1) divided by HR in control C3C (5-17M) Group (HR2)], i. e. 1 - (HR1/HR2).

Comparison groups	C3C (5-17M) Group v RTS,S/AS01 (5-17M)
Number of subjects included in analysis	4296
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	< 0.0001 [3]
Method	Regression, Cox
Parameter estimate	VE (see above)
Point estimate	55.8
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	50.6
upper limit	60.4

Notes:

[2] - Point estimate of efficacy was adjusted for study site as stratification factor for the analysis. This efficacy was calculated with the first 6000 subjects enrolled in the 5-17 months (5-17M) age category. Results were uncorrected for the double enrolment of one subject receiving the RTS,S/AS01 vaccine in the 5-17Ms age category. Criterion for success = lower limit (LL) of 97.5% confidence interval (CI) of VE > 0.

[3] - The p-value presented was calculated using the likelihood ratio test.

Primary: Time to first or only clinical episode of Plasmodium falciparum (P. falciparum) malaria infection (CPFMI), or clinical malaria episode, of Primary Case

Definition (CPFMI-PCD) – In subjects enrolled aged 6-12 weeks	
End point title	Time to first or only clinical episode of Plasmodium falciparum (P. falciparum) malaria infection (CPFMI), or clinical malaria episode, of Primary Case Definition (CPFMI-PCD) – In subjects enrolled aged 6-12 weeks[4]

End point description:

A CPFMI-PCD was defined as an episode of malaria for which P. falciparum asexual parasitemia > 5000 parasites/µL accompanied by 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, the number of CPFMI events reported (n) over the period elapsed until the CPFMI event occurred for each group (T in year = sum of follow-up period expressed in years censored at the first occurrence of event in each group). 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:

[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	C3C (6-12W) Group	RTS,S/AS01 (6-12W) Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	2008	3995		
Units: n/T				
number (not applicable)				
RfoCPFMI-PCD 6-12W M2.5-14	0.484	0.367		

Statistical analyses

Statistical analysis title	Vaccine efficacy (VE) RTS,S/AS01 vs control

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 RTS,S/AS01 (5-17M) Group (HR1) divided by HR in control C3C (5-17M) Group (HR2)], i. e. 1 - (HR1/HR2).

Comparison groups	C3C (6-12W) Group v RTS,S/AS01 (6-12W) Group
Number of subjects included in analysis	6003
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	< 0.0001 [6]
Method	Regression, Cox
Parameter estimate	VE (see above)
Point estimate	31.315
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	23.556
upper limit	38.286

Notes:

[5] - Point estimate of efficacy was adjusted for study site as stratification factor for the analysis. Criterion for success = lower limit (LL) of 97.5% confidence interval (CI) of VE > 0.

[6] - The p-value presented was calculated using the likelihood ratio test.

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of PCD and of secondary case definitions (SCD) 1, SCD 2 and SCD 3

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of PCD and of secondary case definitions (SCD) 1, SCD 2 and SCD 3[7]

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).
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 number of events reported (n) over time (T) elapsed until all events occurred in each group. Results are uncorrected for double enrolment of 1 subject receiving RTS,S/AS01.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 14

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	1466	2008	2830	3995
Units: n/T				
number (not applicable)				
RaCPFMI PCD	1.468	0.908	0.735	0.639
RaCPFMI SCD1	2.312	1.403	1.224	0.989
RaCPFMI SCD2	1.628	1.031	0.847	0.736
RaCPFMI SCD3	1.244	0.731	0.625	0.515

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of PCD, overall and by centre

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of PCD, overall and by centre[8]

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 number of events reported (n) over time (T) elapsed until all events occurred in each group. Results are by centre & across centres, and are uncorrected for double enrolment of 1 subject receiving RTS,S/AS01.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2328	2007	4557	3996
Units: n/T				
number (not applicable)				
RaCPFMI PCD – Agogo (N=192;221;371;418)	1.16	0.79	0.56	0.64
RaCPFMI PCD – Bagamoyo (N=235;244;462;502)	0.28	0.14	0.1	0.08
RaCPFMI PCD – Kilifi (N=171;102;336;186)	0.04	0.02	0.01	0.04
RaCPFMI PCD – Kintampo (N=296;99;602;199)	1.85	1.49	1.01	1.53
RaCPFMI PCD – Kombewa (N=311;196;609;387)	1.87	1.32	1.21	0.94
RaCPFMI PCD – Korogwe (N=293;183;568;382)	0.11	0.05	0.04	0.03
RaCPFMI PCD – Lambarene (N=196;62;380;147)	0.2	0.12	0.11	0.11
RaCPFMI PCD – Lilongwe (N=183;258;359;500)	0.32	0.5	0.2	0.3
RaCPFMI PCD – Manhica (N=0;188;0;381)	0	0.12	0	0.1
RaCPFMI PCD – Nanoro (N=198;225;389;441)	2.4	2.39	1.42	1.93
RaCPFMI PCD – Siaya (N=253;229;481;453)	3.31	2.75	2.01	2.03
RaCPFMI of PCD – Across (N=2328;2007;4557;3996)	1.17	0.92	0.69	0.71

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of SCD1, SCD2 and SCD3, overall

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of SCD1, SCD2 and SCD3, overall[9]

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 number of events reported (n) over time (T) elapsed until all events occurred in each group. Results are across centres, and are uncorrected for double enrolment of 1 subject receiving RTS,S/AS01.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2328	2007	4557	3996
Units: n/T				
number (not applicable)				
RaCPFMI SCD1	1.78	1.42	1.09	1.09
RaCPFMI SCD2	1.3	1.04	0.78	0.81
RaCPFMI SCD3	1.01	0.76	0.59	0.58

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of primary case definition (PCD) by centres & across centres

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of primary case definition (PCD) by centres & across centres

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 number of events reported (n) over time (T) elapsed until all events occurred in each group. Results are by centre & across centres,

End point type	Secondary

End point timeframe:

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

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: n/T				
number (not applicable)				
RaCPFMI PCD – Kilifi (N=163;172;172;90;95;102)	0.02	0.03	0.08	0.06
RaCPFMI PCD – Korogwe (N=286;282;293;191;191;183)	0.04	0.05	0.1	0.05
RaCPFMI PCD – Lamberene (N=187;196;196;72;75;62)	0.15	0.15	0.23	0.1
RaCPFMI PCD – Bagamoyo (N=228;242;236;252;249;245)	0.16	0.21	0.27	0.08
RaCPFMI PCD – Lilongwe (N=176;183;185;247;250;257	0.09	0.2	0.23	0.25
RaCPFMI PCD – Agogo (N=188;183;191;209;209;221)	0.59	0.73	1.01	0.59
RaCPFMI PCD – Kombewa (N=315;301;312;195;193;196)	1.26	1.37	1.64	1.37
RaCPFMI PCD – Kintampo (N=299;310;30198;101;100)	1.11	1.31	1.71	1.65
RaCPFMI PCD – Manhica (N=0;0;0;193;187;188)	0	0	0	0.18
RaCPFMI PCD – Nanoro (N=194;195;198;217;224;224)	1.95	2.18	2.69	2.59
RaCPFMI PCD – Siaya (N=240;242;252;221;231;229)	2.09	2.55	3.15	2.43
RaCPFMI PCD Across(N=2276;23062336;1985;2005;2	0.79	0.9	1.14	0.86

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: n/T				
number (not applicable)				
RaCPFMI PCD – Kilifi (N=163;172;172;90;95;102)	0.04	0.04		
RaCPFMI PCD – Korogwe (N=286;282;293;191;191;183)	0.07	0.09		
RaCPFMI PCD – Lamberene (N=187;196;196;72;75;62)	0.18	0.17		
RaCPFMI PCD – Bagamoyo (N=228;242;236;252;249;245)	0.11	0.15		
RaCPFMI PCD – Lilongwe (N=176;183;185;247;250;257	0.29	0.42		
RaCPFMI PCD – Agogo (N=188;183;191;209;209;221)	0.77	0.84		
RaCPFMI PCD – Kombewa (N=315;301;312;195;193;196)	1.37	1.62		
RaCPFMI PCD – Kintampo (N=299;310;30198;101;100)	1.71	1.69		
RaCPFMI PCD – Manhica (N=0;0;0;193;187;188)	0.14	0.2		
RaCPFMI PCD – Nanoro (N=194;195;198;217;224;224)	2.79	3.14		

RaCPFMI PCD – Siaya (N=240;242;252;221;231;229)	2.67	3.12		
RaCPFMI PCD Across(N=2276;23062336;1985;2005;2	0.95	1.08		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of Secondary Case Definition 1 (SCD1) and Primary Case Definition (PCD1) – across centres;

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of Secondary Case Definition 1 (SCD1) and Primary Case Definition (PCD1) – across centres;

End point description:

CPFMI of SCD1 = malaria episode with PFAP>0 & 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 number of events reported (n) over time (T) elapsed until all events occurred in each group. Results are presented across centres,

End point type	Secondary

End point timeframe:

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

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: n/T				
number (not applicable)				
RaCPFMI SCD1	1.26	1.41	1.81	1.29

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: n/T				
number (not applicable)				
RaCPFMI SCD1	1.43	1.61		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of Primary Case Definition (PCD) and Secondary Case Definition 1 (SCD1)

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of Primary Case Definition (PCD) and Secondary Case Definition 1 (SCD1)

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.
CPFMI of SCD1 = malaria episode with PFAP>0 & 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 number of events reported (n) over time (T) elapsed until all events occurred in each group. Results are across centres,

End point type	Secondary

End point timeframe:

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

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2017	2057	2050	1743
Units: n/T				
number (not applicable)				
RaCPFMI PCD	0.87	1.03	1.1	1.01
RaCPFMI SCD1	1.39	1.65	1.82	1.48

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1788	1762		
Units: n/T				
number (not applicable)				
RaCPFMI PCD	1.21	1.23		
RaCPFMI SCD1	1.79	1.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of PCD and SCD1 across centres

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of PCD and SCD1 across centres

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.
CPFMI of SCD1 = malaria episode with PFAP>0 & 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 number of events reported (n) over time (T) elapsed until all events occurred in each group. Results are across centres,

End point type	Secondary

End point timeframe:

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

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1784	1838	1864	1516
Units: n/T				
number (not applicable)				
RaCPFMI PCD (N=1784;1838;1864;1516;1548;1546)	1.01	1.1	1.1	1.18
RaCPFMI SCD1 (N=1784;1838;1864;1516;1547;1546)	1.61	1.79	1.88	1.73

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1548	1546		
Units: n/T				
number (not applicable)				
RaCPFMI PCD (N=1784;1838;1864;1516;1548;1546)	1.31	1.29		
RaCPFMI SCD1 (N=1784;1838;1864;1516;1547;1546)	1.92	1.91		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of PCD –by centre & across centres

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of PCD –by centre & across centres

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 number of events reported (n) over time (T) elapsed until all events occurred in each group. Results are by centre & across centres

End point type	Secondary
End point timeframe:	
From Month 2.5 to Month 32	

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: n/T				
number (not applicable)				
RaCPFMI PCD – Kilifi (N=163;172;172;90;95;102)	0.03	0.04	0.09	0.06
RaCPFMI PCD – Korogwe (N=286;282;293;191;191;183)	0.04	0.03	0.08	0.02
RaCPFMI PCD – Lamberene (N=187;196;196;72;75;62)	0.14	0.14	0.21	0.1
RaCPFMI PCD – Bagamoyo (N=228;242;236;252;249;246)	0.13	0.19	0.31	0.08
RaCPFMI PCD – Lilongwe (N=176;183;185;247;250;257	0.11	0.22	0.29	0.27
RaCPFMI PCD – Agogo (N=188;183;191;209;209;221)	0.59	0.75	1.15	0.56
RaCPFMI PCD – Kombewa (N=315;301;312;195;193;196)	1.12	1.29	1.67	1.28
RaCPFMI PCD – Kintampo (N=299;310;301;98;101;100)	1.08	1.17	1.87	1.52
RaCPFMI PCD – Manhica (N=0;0;0;193;187;188)	0	0	0	0.15
RaCPFMI PCD – Nanoro (N=194;195;198;217;224;224)	1.42	1.67	2.45	2.27
RaCPFMI PCD – Siaya (N=954;242;252;221;231;229)	1.91	2.46	3.25	2.41
RaCPFMI PCDAcross(N=2276;2306;2336;1985;2	0.68	0.81	1.15	0.8

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: n/T				
number (not applicable)				
RaCPFMI PCD – Kilifi (N=163;172;172;90;95;102)	0.04	0.05		
RaCPFMI PCD – Korogwe (N=286;282;293;191;191;183)	0.06	0.06		
RaCPFMI PCD – Lamberene (N=187;196;196;72;75;62)	0.18	0.18		
RaCPFMI PCD – Bagamoyo (N=228;242;236;252;249;246)	0.11	0.15		
RaCPFMI PCD – Lilongwe (N=176;183;185;247;250;257	0.32	0.47		

RaCPFMI PCD – Agogo (N=188;183;191;209;209;221)	0.72	0.86		
RaCPFMI PCD – Kombewa (N=315;301;312;195;193;196)	1.25	1.55		
RaCPFMI PCD – Kintampo (N=299;310;301;98;101;100)	1.6	1.6		
RaCPFMI PCD – Manhica (N=0;0;0;193;187;188)	0.12	0.15		
RaCPFMI PCD – Nanoro (N=194;195;198;217;224;224)	2.53	2.92		
RaCPFMI PCD – Siaya (N=954;242;252;221;231;229)	2.54	3.09		
RaCPFMI PCDAcross(N=2276;2306;2336;1985;2	0.88	1.03		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of Secondary Case Definition 1 (SCD1)

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of Secondary Case Definition 1 (SCD1)

End point description:

CPFMI of SCD1 = malaria episode with PFAP>0 & 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, number of CPFMI events reported (n) over period elapsed until all CPFMI events reported occurred for each group (T in year = sum of FU period in years censored at last occurrence of event in each group). Analysis was performed on subjects aged 5-17 months at enrolment.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 32

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: n/T				
number (not applicable)				
RaCPFMI SCD1	1.1	1.24	1.78	1.19

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: n/T				
number (not applicable)				
RaCPFMI SCD1	1.33	1.54		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of Primary Case Definition (PCD) and Secondary Case Definition 1 (SCD1)

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of Primary Case Definition (PCD) and Secondary Case Definition 1 (SCD1)

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. CPFMI of SCD1 = malaria episode with PFAP>0 & 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, number of CPFMI events reported (n) over period elapsed until all CPFMI events reported occurred for each group (T in year = sum of FU period in years censored at last occurrence of event in each group). Analysis was performed on subjects aged 5-17 months at enrolment.

End point type	Secondary

End point timeframe:

From Booster at Month 20 to Month 32.

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2017	2057	2050	1743
Units: n/T				
number (not applicable)				
RaCPFMI PCD	0.72	0.96	1.1	0.91
RaCPFMI SCD1	1.14	1.48	1.74	1.35

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1788	1762		
Units: n/T				
number (not applicable)				
RaCPFMI PCD	1.15	1.2		
RaCPFMI SCD1	1.72	1.74		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

SPFMI of PCD = PFMI>5000 parasites/µL, at least one severity marker & 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, & without co-morbidity or HIV.
Severity markers = prostration; respiratory distress; Blantyre score =< 2; ≥ 2 seizures in 24 h prior to admission, emergency room & 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. A Analysis was performed in a pooled manner across age categories. Results presented are uncorrected for double enrolment of one subject in 5-17 months age category receiving RTS,S/AS01.

End point type	Secondary

End point timeframe:

From Month 2.5 up to time when 250 subjects diagnosed with severe malaria of PCD, SCD1, SCD2 and SCD3

End point values	RTS,S/AS01 Group	C3C Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8597	4364		
Units: percentage				
number (not applicable)				
SPFMI PCD	0.019	0.03		
SPFMI SCD1	0.023	0.036		
SPFMI SCD2	0.023	0.034		
SPFMI 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[10]

End point description:

SPFMI of PCD = PFMI>5000 parasites/µL, at least one severity marker & 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 & 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 & 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 enrolment of one subject in 5-17 months age category recei

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 14

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	1466	2008	2830	3995
Units: percentage				
number (not applicable)				
SPFMI PCD	3.8	2.3	2	1.5
SPFMI SCD1	4.9	2.5	2.6	1.6

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[11]

End point description:

SPFMI of PCD = PFMI>5000 parasites/µL, at least one severity marker & 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 & 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 & 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 enrolment 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

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2328	2007	4557	3996
Units: percentage				
number (not applicable)				
SPFMI PCD	0.04	0.03	0.03	0.03
SPFMI SCD1	0.05	0.03	0.03	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 & 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 & 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 & 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 to study end, from booster (Month 20) to study end, from Month 33 to study end and from Month 2.5 to Month 32 and Month 20 (booster) to Month 32

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: percentage				
number (not applicable)				
PCD, M2.5 to SE (N=2276;2306;2336;1985;2005;2007)	0.04	0.06	0.06	0.04
PCD, M20 to SE (N=2017;2057;2051;1743;1788;1762)	0.03	0.04	0.02	0.02
PCD, M33 to SE (N=1784;1838;1864;1516;1548;1546)	0.01	0.02	0.01	0.01
PCD, M2.5 to M32 (N=2276;2306;2336;1985;2005;2007)	0.03	0.05	0.05	0.04
PCD M20 to M32 (N=2017;2057;2051;1743;1788;1762)	0.02	0.02	0.02	0.01
SCD1, M2.5 to SE (N=2276;2306;2336;1985;2005;2007)	0.05	0.07	0.07	0.04
SCD1, M20 to SE (N=2017;2057;2051;1743;1788;1762)	0.03	0.04	0.03	0.02

SCD1, M33 to SE(N=1784;1838;1864;1516;1548;154	0.01	0.02	0.01	0.01
SCD1 M2.5 to M32 (N=2276;2306;2336;1985;2005;2007)	0.04	0.06	0.06	0.04
SCD1 M20 to M32 (N=2017;2057;2051;1743;1788;1762)	0.02	0.03	0.02	0.01

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: percentage				
number (not applicable)				
PCD, M2.5 to SE (N=2276;2306;2336;1985;2005;2007)	0.04	0.05		
PCD, M20 to SE (N=2017;2057;2051;1743;1788;1762)	0.03	0.03		
PCD, M33 to SE (N=1784;1838;1864;1516;1548;1546)	0.01	0.01		
PCD, M2.5 to M32 (N=2276;2306;2336;1985;2005;2007)	0.04	0.04		
PCD M20 to M32 (N=2017;2057;2051;1743;1788;1762)	0.02	0.02		
SCD1, M2.5 to SE (N=2276;2306;2336;1985;2005;2007)	0.05	0.06		
SCD1, M20 to SE (N=2017;2057;2051;1743;1788;1762)	0.03	0.03		
SCD1, M33 to SE(N=1784;1838;1864;1516;1548;154	0.01	0.01		
SCD1 M2.5 to M32 (N=2276;2306;2336;1985;2005;2007)	0.04	0.05		
SCD1 M20 to M32 (N=2017;2057;2051;1743;1788;1762)	0.02	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[12]

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 enrolment of one subject in 5-17 months age category receiving RTS,S/AS01.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2328	2007	4557	3996
Units: percentage				
number (not applicable)				
ISA CD1	0.01	0.01	0.01	0.01
MH CD1	0.09	0.05	0.05	0.04
MH CD2	0.1	0.06	0.06	0.05

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

End point description:

ISA CD considered were CD1, CD2 and CD3. 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. ISA of CD2 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 > 0 parasites/µL ISA of CD3 was defined as a documented hemoglobin < 5.0 g/dL identified at clinical presentation to morbidity surveillance system.
MH CD considered were CD1 and CD2. 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.
FM CD considered were primary CD (PCD) and sedondary CDs 1 and 4 (SCD1 and SCD4). FM of PCD was defined as

End point type	Secondary

End point timeframe:

From Month 2.5 to Study End

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: percentage				
number (not applicable)				
ISA CD1	0.01	0.01	0.02	0.01
ISA CD2	0.01	0.02	0.02	0.01
ISA CD3	0.02	0.02	0.02	0.02

MH CD1	0.07	0.1	0.12	0.06
MH CD2	0.09	0.11	0.13	0.08
FM PCD	0	0	0	0
FM SCD1	0	0	0	0
FM SCD4	0	0	0	0

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: percentage				
number (not applicable)				
ISA CD1	0.01	0.02		
ISA CD2	0.02	0.02		
ISA CD3	0.03	0.03		
MH CD1	0.07	0.08		
MH CD2	0.09	0.1		
FM PCD	0	0		
FM SCD1	0	0		
FM SCD4	0.01	0		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

ISA CD considered were CD1, CD2 and CD3. 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. ISA of CD2 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 > 0 parasites/µL ISA of CD3 was defined as a documented hemoglobin < 5.0 g/dL identified at clinical presentation to morbidity surveillance system.
MH CD considered were CD1 and CD2. 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.
FM CD considered were primary CD (PCD) and sedondary CDs 1 and 4 (SCD1 and SCD4). FM of PCD was defined as

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 32

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: percentage				
number (not applicable)				
ISA CD1	0.01	0.01	0.01	0.01
ISA CD2	0.01	0.01	0.02	0.01
ISA CD3	0.01	0.02	0.02	0.02
MH CD1	0.06	0.09	0.11	0.05
MH CD2	0.08	0.1	0.12	0.07
FM PCD	0	0	0	0
FM SCD1	0	0	0	0
FM SCD4	0	0	0	0

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: percentage				
number (not applicable)				
ISA CD1	0.01	0.01		
ISA CD2	0.01	0.01		
ISA CD3	0.02	0.02		
MH CD1	0.06	0.07		
MH CD2	0.08	0.09		
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[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 at timing of assessmentResults presented are uncorrected for the double enrolment of one subject receiving RTS,S/AS01.

End point type	Secondary

End point timeframe:

At Month 20 (Booster)

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2100	1766	4140	3571
Units: percentage				
number (not applicable)				
PP (N=2100;1766;4140;3571)	0.11	0.08	0.07	0.07
PSA (N=2097;1765;4139;3571)	0	0	0	0
PMA (N=2097;1765;4139;3571)	0.03	0.04	0.03	0.04
PG (N=2025;0;4021;0)	0.04	0	0.03	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

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 enrolment. 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 Month (M) 32, at (M) 44, at Study End (SE) (Early) and at SE (Late)

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1935	1967	1979	1637
Units: percentage				
number (not applicable)				
PP M32 (N=1935;1963;1976;1635;1656;1647)	0.09	0.1	0.14	0.09
PSA M32 (N=1934;1967;1979;1637;1655;1648)	0	0	0	0

PMA M32 (N=1934;1967;1979;1637;1655;1648)	0.02	0.02	0.02	0.02
PP M44 (N=1039;1072;1093;0;0;0)	0.16	0.17	0.2	0
PSA M44 (N=1041;1072;1094;0;0;0)	0	0	0	0
PMA M44 (N=1041;1072;1094;0;0;0)	0.01	0.02	0.01	0
PP SE (Early) (N=681;661;672;1481;1472;1487)	0.09	0.1	0.14	0.11
PSA SE (Early) (N=681;661;672;1481;1472;1486)	0	0	0	0
PMA SE (Early) (N=681;661;672;1481;1472;1486)	0.01	0.02	0.03	0.03
PP SE (Late) (N=1054;1059;1104;0;0;0)	0.18	0.18	0.21	0
PSA SE (Late) (N=1053;1057;1104;0;0;0)	0	0	0	0
PMA SE (Late) (N=1053;1057;1104;0;0;0)	0.03	0.03	0.02	0

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1656	1648		
Units: percentage				
number (not applicable)				
PP M32 (N=1935;1963;1976;1635;1656;1647)	0.11	0.1		
PSA M32 (N=1934;1967;1979;1637;1655;1648)	0	0		
PMA M32 (N=1934;1967;1979;1637;1655;1648)	0.04	0.03		
PP M44 (N=1039;1072;1093;0;0;0)	0	0		
PSA M44 (N=1041;1072;1094;0;0;0)	0	0		
PMA M44 (N=1041;1072;1094;0;0;0)	0	0		
PP SE (Early) (N=681;661;672;1481;1472;1487)	0.14	0.13		
PSA SE (Early) (N=681;661;672;1481;1472;1486)	0	0		
PMA SE (Early) (N=681;661;672;1481;1472;1486)	0.03	0.03		
PP SE (Late) (N=1054;1059;1104;0;0;0)	0	0		
PSA SE (Late) (N=1053;1057;1104;0;0;0)	0	0		
PMA SE (Late) (N=1053;1057;1104;0;0;0)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of severe PFMI (SPFMI) of primary case definition (PCD) and secondary case definition (SCD1; SCD2; SCD3) across centres

End point title	Time to all episodes of severe PFMI (SPFMI) of primary case definition (PCD) and secondary case definition (SCD1; SCD2; SCD3) across centres

End point description:

SPFMI of PCD = PFMI>5000 parasites/µL, at least one severity marker & 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, & without co-morbidity or HIV.
Severity markers = prostration; respiratory distress; Blantyre score =< 2; ≥ 2 seizures in 24 h prior to admission, emergency room & hospitalisation; hypoglycaemia<2.2 mmol/L; acidosis BE -10.0 mmol/L,l 5.0 mmol/L; anaemia<5.0 g/dL. Co-morbidities = radiographically proven pneumonia; meningitis; positive blood culture on a blood culture taken within 72 h of admission; gastroenteritis with dehydration. Time to all episodes of SPFMI is expressed as a rate of all SPFMI (RaSPFMI), that is, number of events reported (n) over period elapsed until all events reported occurred for each group (T in year = sum of FU perio

End point type	Secondary

End point timeframe:

From Month 2.5 up to time when 250 subjects diagnosed with severe malaria of PCD; SCD1; SCD2; SCD3

End point values	RTS,S/AS01 Group	C3C Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8597	4364		
Units: n/T				
number (not applicable)				
RaSPFMI PCD	0.019	0.03		
RaSPFMI SCD1	0.023	0.036		
RaSPFMI SCD2	0.023	0.034		
RaSPFMI SCD3	0.019	0.03		

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[14]

End point description:

Pneumonia case definitions assessed are primary case definition (PCD) and secondary case definitions (SCD) 1, 2 and 3. 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. 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 less than 90%. Results presented are uncorrected for double enrolment of one subject in 5-17 months age category receiving RTS,S/AS01.
All-cause hospitalization case definition assessed was the primary case definition (PCD).
All-cause hospitalization of PCD was defined as a

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2328	2007	4557	3996
Units: percentage				
number (not applicable)				
Pneumonia PCD	0.03	0.04	0.03	0.04
Pneumonia SCD1	0	0.01	0.01	0.01
Pneumonia SCD2	0.02	0.03	0.02	0.03
Pneumonia SCD3	0.01	0.01	0	0.01
All-Cause Hospitalization PCD	0.19	0.19	0.15	0.18
Sepsis CD1	0.02	0.01	0.02	0.02
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[15]

End point description:

Fatal malaria case definitions assessed were the primary case definition (PCD) and the secondary case definition (SCD) 1. Fatal malaria of PCD was defined as a case of severe malaria meeting the primary case definition of severe malaria disease (see above endpoint for definition) 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 (see above endpoint for definition) 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 enrolment of one subject in 5-17 months age category receivi

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 20

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2328	2007	4557	3996
Units: percentage				
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

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 to Study End

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: percentage				
number (not applicable)				
All-Cause Hospitalization PCD	0.21	0.22	0.24	0.23
Sepsis CD 1	0.02	0.02	0.03	0.02
Sepsis CD 2	0.01	0.01	0.02	0.01
Pneumonia PCD	0.04	0.03	0.03	0.05
Pneumonia SCD1	0.01	0.01	0.01	0.01
Pneumonia SCD2	0.03	0.02	0.02	0.03
Pneumonia SCD3	0	0	0.01	0.01
All-Cause Mortality CD1	0.01	0.01	0.01	0.02

All-Cause Mortality CD2	0.01	0.01	0.01	0.02

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: percentage				
number (not applicable)				
All-Cause Hospitalization PCD	0.23	0.24		
Sepsis CD 1	0.02	0.02		
Sepsis CD 2	0.02	0.01		
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	0.01		
All-Cause Mortality CD2	0.02	0.01		

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

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 to Study End

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: percentage				
number (not applicable)				
Blood transfusion CD1	0.03	0.03	0.04	0.03

End point values	R3C (6-12W) Group	C3C (6-12W) Group		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: percentage				
number (not applicable)				
Blood transfusion CD1	0.03	0.04		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of primary case definition (PCD) by gender & overall

End point title	Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of primary case definition (PCD) by gender & overall

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, number of CPFMI events reported (n) over period elapsed until all CPFMI events reported occurred for each group (T in year = sum of FU period in years censored at last occurrence of event in each group). Analysis was performed on subjects aged 5-17 months at enrolment and of 6-12 weeks. Results presented are by gender and overall.

End point type	Secondary

End point timeframe:

From Month 2.5 to Month 32

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2276	2306	2336	1985
Units: n/T				
number (not applicable)				
RaCPFMI PCD Females(N=1123;1137;1167;967;976;1	0.72	0.8	1.11	0.76
RaCPFMI PCD Males(N=1153;1169;1169;1018;1029;9	0.65	0.81	1.19	0.83
RaCPFMI PCDOverall(N=2276;2306;2336;1985;2	0.68	0.81	1.15	0.8

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2005	2007		
Units: n/T				
number (not applicable)				

RaCPFMI PCD Females(N=1123;1137;1167;967;976;1	0.79	1.06		
RaCPFMI PCD Males(N=1153;1169;1169;1018;1029;9	0.96	1.01		
RaCPFMI PCDOverall(N=2276;2306;2336;1985;2	0.88	1.03		

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)[16]

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] (low weight for age z-score ≤-2, very low weight for age ≤-3) and mid-upper arm circumference for age z-score [MUACZ] measurements.

End point type	Secondary

End point timeframe:

At Month 20 (Booster)

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2974	2179	5949	4358
Units: z-score				
arithmetic mean (standard deviation)				
HAZ	-1.6 (± 1)	-1.7 (± 1.2)	-1.6 (± 1)	-1.7 (± 1.1)
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)

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] (low weight for age z-score

≤-2, very low weight for age ≤-3) and mid-upper arm circumference for age z-score [MUACZ] measurements.

End point type	Secondary

End point timeframe:

At Month (M) 32, at (M) 44, at Study End (SE) (Early) and at SE (Late)

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2363	2382	2392	1726
Units: z-score				
arithmetic mean (standard deviation)				
HAZ (M 32) [2363;2382;2392;1726;1731;1725]	-1.3 (± 1)	-1.4 (± 1)	-1.4 (± 1)	-1.5 (± 1.1)
WAZ (M32) [2363;2382;2392;1726;1731;1725]	-0.9 (± 0.9)	-1 (± 0.9)	-1 (± 0.9)	-0.9 (± 1)
MUACZ (M32) [2363;2382;2392;1726;1731;1725]	-0.4 (± 0.9)	-0.4 (± 0.9)	-0.4 (± 0.8)	-0.4 (± 0.9)
HAZ (M 44) [1275;1289;1307;0;0;0]	-1.1 (± 1)	-1.2 (± 0.9)	-1.2 (± 1)	0 (± 0)
WAZ (M44) [1275;1289;1307;0;0;0]	-0.9 (± 0.9)	-1 (± 0.9)	-0.9 (± 0.8)	0 (± 0)
MUACZ (M44) [1275;1289;1307;0;0;0]	-0.7 (± 0.8)	-0.7 (± 0.9)	-0.6 (± 0.8)	0 (± 0)
HAZ (SE early) [774;755;768;1555;1533;1549]	-1.3 (± 1)	-1.3 (± 1)	-1.3 (± 1)	-1.4 (± 1)
WAZ (SE early) [774;755;768;1555;1533;1549]	-1 (± 0.8)	-1 (± 0.8)	-1 (± 0.8)	-0.9 (± 0.9)
MUACZ (SE early) [774;755;768;1555;1533;1549]	-0.8 (± 0.9)	-0.8 (± 0.9)	-0.8 (± 0.8)	-0.5 (± 0.9)
HAZ (SE late) [1290;1283;1317;0;0;0]	-1 (± 0.9)	-1.1 (± 0.9)	-1.1 (± 1)	0 (± 0)
WAZ (SE late) [1290;1283;1317;0;0;0]	-0.9 (± 0.9)	-1 (± 0.9)	-1 (± 0.8)	0 (± 0)
MUACZ (SE late) [1290;1283;1317;0;0;0]	-0.7 (± 0.8)	-0.8 (± 0.9)	-0.7 (± 0.8)	0 (± 0)

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1731	1725		
Units: z-score				
arithmetic mean (standard deviation)				
HAZ (M 32) [2363;2382;2392;1726;1731;1725]	-1.4 (± 1.1)	-1.5 (± 1.1)		
WAZ (M32) [2363;2382;2392;1726;1731;1725]	-0.9 (± 1)	-0.9 (± 1)		
MUACZ (M32) [2363;2382;2392;1726;1731;1725]	-0.3 (± 1)	-0.4 (± 1)		
HAZ (M 44) [1275;1289;1307;0;0;0]	0 (± 0)	0 (± 0)		
WAZ (M44) [1275;1289;1307;0;0;0]	0 (± 0)	0 (± 0)		
MUACZ (M44) [1275;1289;1307;0;0;0]	0 (± 0)	0 (± 0)		
HAZ (SE early) [774;755;768;1555;1533;1549]	-1.4 (± 1)	-1.4 (± 1)		
WAZ (SE early) [774;755;768;1555;1533;1549]	-0.9 (± 0.9)	-0.9 (± 0.9)		

MUACZ (SE early) [774;755;768;1555;1533;1549]	-0.4 (± 0.9)	-0.5 (± 0.9)		
HAZ (SE late) [1290;1283;1317;0;0;0]	0 (± 0)	0 (± 0)		
WAZ (SE late) [1290;1283;1317;0;0;0]	0 (± 0)	0 (± 0)		
MUACZ (SE late) [1290;1283;1317;0;0;0]	0 (± 0)	0 (± 0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti Plasmodium falciparum circumsporozoite (anti-CS) antibody concentrations in the 1st 200 subjects in each center

End point title	Anti Plasmodium falciparum circumsporozoite (anti-CS) antibody concentrations in the 1st 200 subjects in each center[17]

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 greater than or equal to (≥) 0.5 EL.U/mL. Results were assessed in the 1st 200 subjects enrolled in each study center.

End point type	Secondary

End point timeframe:

At baseline & M3

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	529	627	1036	1234
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS (Screening) [N=526;627;1036;1234]	0.3 (0.3 to 0.3)	0.4 (0.4 to 0.5)	0.3 (0.3 to 0.3)	0.4 (0.4 to 0.4)
Anti-CS (PIII[M3]) [N=529;627;1034;1221]	0.3 (0.3 to 0.3)	0.3 (0.3 to 0.3)	621 (591.5 to 651.9)	210.5 (198.2 to 223.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-CS antibody concentrations in the 1st 200 HIV-infected subjects in each center

End point title	Anti-CS antibody concentrations in the 1st 200 HIV-infected subjects in each center[18]

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 greater than or equal to (≥) 0.5 EL.U/mL. Results were assessed in the 1st 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 baseline & M3

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	17	5	29	25
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS (Screening) [N=16;5;28;25]	0.4 (0.3 to 0.5)	0.3 (0.3 to 0.3)	0.3 (0.2 to 0.5)	0.3 (0.2 to 0.4)
Anti-CS (PIII[M3]) [N=17;5;29;24]	0.5 (0.2 to 1.7)	0.3 (0.3 to 0.3)	264.7 (137.5 to 509.6)	125.3 (58.1 to 270.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-CS antibody concentrations across sites

End point title	Anti-CS antibody concentrations across sites

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 greater than or equal to (≥) 0.5 EL.U/mL.

End point type	Secondary

End point timeframe:

At M20, M21 & M32

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	61	60	66
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS Agogo (PIII[M20]) [55;57;54;55;55;66]	34.1 (24 to 48.3)	52.1 (41.3 to 65.7)	0.3 (0.3 to 0.4)	5.1 (3.4 to 7.6)

Anti-CS Agogo (PIV[M21]) [51;53;53;55;55;65]	265 (220.9 to 317.9)	48.3 (37.6 to 61.9)	0.3 (0.2 to 0.3)	137.6 (95 to 199.3)
Anti-CS Agogo (PIV[M32]) [53;54;54;52;53;64]	46.3 (34.8 to 61.6)	28.8 (21.8 to 37.9)	0.3 (0.2 to 0.3)	14.8 (9.5 to 23.1)
Anti-CS Bagamoyo (PIII[M20]) [16;18;25;47;54;42]	26.6 (14.2 to 49.9)	23.1 (11.1 to 47.8)	0.3 (0.3 to 0.3)	6.9 (4.8 to 10)
Anti-CS Bagamoyo (PIV[M21]) [16;18;24;46;53;42]	306.6 (206.5 to 455.4)	31.8 (19.4 to 52.2)	0.6 (0.2 to 1.4)	169.9 (129.8 to 222.5)
Anti-CS Bagamoyo (PIV[M32]) [16;17;24;43;49;40	44.6 (27.2 to 73.3)	16.9 (10.2 to 27.9)	0.3 (0.3 to 0.3)	14.4 (9.6 to 21.7)
Anti-CS Kilifi (PIII[M20]) [N=43;50;42;43;56;53]	34.3 (26.3 to 44.7)	33.1 (26.3 to 41.6)	0.3 (0.3 to 0.3)	6.6 (4.6 to 9.6)
Anti-CS Kilifi (PIV[M21]) [N=40;49;41;41;54;51]	308.4 (251.8 to 377.7)	24.3 (18.1 to 32.8)	0.3 (0.3 to 0.3)	229.3 (175.4 to 299.9)
Anti-CS Kilifi (PIV[M32]) [N=42;47;39;42;51;50]	59.4 (45.7 to 77.2)	14.9 (11 to 20.2)	0.3 (0.3 to 0.4)	19.8 (14.1 to 27.8)
Anti-CS Kintampo (PIII[M20]) [N=57;51;52;52;55;46]	50.8 (37.2 to 69.5)	36.6 (26.4 to 50.7)	0.4 (0.3 to 0.5)	3.8 (2.5 to 5.8)
Anti-CS Kintampo (PIV[M21]) [N=54;47;47;47;50;43]	266.8 (188.9 to 377)	41.2 (31.2 to 54.6)	0.3 (0.2 to 0.3)	128.8 (95.7 to 173.4)
Anti-CS Kintampo (PIV[M32]) [N=50;46;49;47;47;42]	70.9 (55.2 to 90.9)	20.2 (14.3 to 28.5)	0.4 (0.3 to 0.5)	13.3 (8.1 to 21.9)
Anti-CS Kombewa (PIII[M20]) [N=54;50;60;54;54;54]	39.8 (29.9 to 53)	46.6 (33.2 to 65.3)	0.3 (0.3 to 0.4)	5.5 (3.6 to 8.4)
Anti-CS Kombewa (PIV[M21]) [N=52;50;59;50;51;52]	308.5 (252.4 to 377)	37.1 (26.7 to 51.5)	0.4 (0.3 to 0.4)	146.3 (96.6 to 221.6)
Anti-CS Kombewa (PIV[M32]) [N=48;46;56;46;48;51]	53.8 (40.3 to 71.7)	19.8 (14.1 to 27.7)	0.3 (0.3 to 0.4)	8.3 (4.8 to 14.3)
Anti-CS Korogwe (PIII[M20]) [N=55;61;52;52;48;57]	29.4 (21.4 to 40.4)	28.2 (22.5 to 35.3)	0.3 (0.3 to 0.3)	7.9 (5.3 to 11.8)
Anti-CS Korogwe (PIV[M21]) [N=50;61;48;50;46;54]	305.6 (266.4 to 350.5)	27.1 (20.7 to 35.5)	0.3 (0.2 to 0.3)	178.3 (141.2 to 225.1)
Anti-CS Korogwe (PIV[M32]) [N=52;56;44;49;42;48]	47.4 (37.5 to 59.9)	16.8 (13.1 to 21.7)	0.3 (0.2 to 0.3)	19.6 (13 to 29.6)
Anti-CS Lambarene (PIII[M20]) [N=32;30;29;44;46;39	8.2 (5.8 to 11.6)	11.1 (7 to 17.6)	0.3 (0.2 to 0.3)	7.7 (5.1 to 11.6)
Anti-CS Lambarene (PIV[M21]) [N=32;30;29;43;45;35]	203.6 (155.1 to 267.3)	10.6 (6.6 to 16.8)	0.3 (0.2 to 0.3)	251.3 (184.8 to 341.7)
Anti-CS Lambarene (PIV[M32]) [N=29;29;27;38;43;33]	23 (15.6 to 33.9)	5.9 (3.6 to 9.9)	0.3 (0.2 to 0.4)	21 (13.9 to 31.7)
Anti-CS Lilongwe (PIII[M20]) [N=21;17;25;48;46;53]	45.9 (28.6 to 73.8)	22.2 (11.2 to 44)	0.4 (0.2 to 0.7)	5.1 (3.2 to 8.3)
Anti-CS Lilongwe (PIV[M21]) [N=23;15;24;44;45;51]	285 (228.5 to 355.4)	17 (8.1 to 35.7)	0.3 (0.2 to 0.4)	126.1 (92.7 to 171.5)
Anti-CS Lilongwe (PIV[M32]) [N=19;16;22;45;46;50]	45.6 (28.8 to 72.3)	12.7 (6.4 to 25.3)	0.3 (0.2 to 0.4)	15.4 (9.3 to 25.4)
Anti-CS Nanoro (PIII[M20]) [N=63;60;56;50;69;53]	57.2 (43.4 to 75.4)	61.8 (46.3 to 82.4)	0.3 (0.3 to 0.3)	2.7 (1.7 to 4.4)
Anti-CS Nanoro (PIV[M21]) [N=63;60;56;50;68;53]	520.5 (443.4 to 611.1)	71.1 (54.8 to 92.3)	0.3 (0.2 to 0.3)	163.2 (121.4 to 219.4)
Anti-CS Nanoro (PIV[M32]) [N=60;57;51;45;66;51]	69.2 (55.2 to 86.9)	35 (25.7 to 47.9)	0.3 (0.3 to 0.3)	11.9 (7.4 to 19.2)
Anti-CS Siaya (PIII[M20]) [N=46;44;31;40;40;48]	28.4 (18.4 to 44)	32.8 (21.6 to 50.1)	0.3 (0.3 to 0.4)	7 (4.2 to 11.5)
Anti-CS Siaya (PIV[M21]) [N=45;42;28;41;39;45]	398.1 (324.6 to 488.2)	36.4 (22.6 to 58.6)	0.3 (0.2 to 0.4)	171.5 (109.8 to 267.9)
Anti-CS Siaya (PIV[M32]) [N=45;40;27;36;36;42]	55.8 (41.4 to 75.3)	21.7 (13.4 to 35.1)	0.4 (0.3 to 0.5)	23.6 (14.2 to 39.1)
Anti-CS Manhica (PIII[M20]) [N=0;0;0;45;46;43]	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	12.3 (8.4 to 18.1)
Anti-CS Manhica (PIV[M21]) [N=0;0;0;36;38;28]	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	260.2 (176.4 to 383.8)

Anti-CS Manhica (PIV[M32]) [N=0;0;0;35;34;30]	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	25.4 (14.8 to 43.5)

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	64		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS Agogo (PIII[M20]) [55;57;54;55;55;66]	5.6 (3.8 to 8.4)	0.3 (0.2 to 0.3)		
Anti-CS Agogo (PIV[M21]) [51;53;53;55;55;65]	5.3 (3.5 to 8)	0.3 (0.2 to 0.3)		
Anti-CS Agogo (PIV[M32]) [53;54;54;52;53;64]	2.9 (1.9 to 4.5)	0.3 (0.3 to 0.4)		
Anti-CS Bagamoyo (PIII[M20]) [16;18;25;47;54;42]	7.6 (5.1 to 11.4)	0.3 (0.2 to 0.3)		
Anti-CS Bagamoyo (PIV[M21]) [16;18;24;46;53;42]	7.2 (4.5 to 11.6)	0.3 (0.2 to 0.4)		
Anti-CS Bagamoyo (PIV[M32]) [16;17;24;43;49;40	3.7 (2.4 to 5.7)	0.3 (0.3 to 0.3)		
Anti-CS Kilifi (PIII[M20]) [N=43;50;42;43;56;53]	6.1 (4 to 9.4)	0.3 (0.2 to 0.3)		
Anti-CS Kilifi (PIV[M21]) [N=40;49;41;41;54;51]	5.3 (3.4 to 8.2)	0.3 (0.3 to 0.3)		
Anti-CS Kilifi (PIV[M32]) [N=42;47;39;42;51;50]	2.8 (1.8 to 4.4)	0.3 (0.3 to 0.3)		
Anti-CS Kintampo (PIII[M20]) [N=57;51;52;52;55;46]	3.7 (2.5 to 5.6)	0.3 (0.3 to 0.4)		
Anti-CS Kintampo (PIV[M21]) [N=54;47;47;47;50;43]	3.2 (2 to 5)	0.3 (0.3 to 0.4)		
Anti-CS Kintampo (PIV[M32]) [N=50;46;49;47;47;42]	2.2 (1.4 to 3.4)	0.3 (0.3 to 0.3)		
Anti-CS Kombewa (PIII[M20]) [N=54;50;60;54;54;54]	8.7 (5.8 to 13)	0.4 (0.3 to 0.5)		
Anti-CS Kombewa (PIV[M21]) [N=52;50;59;50;51;52]	9.2 (6 to 14.2)	0.4 (0.3 to 0.5)		
Anti-CS Kombewa (PIV[M32]) [N=48;46;56;46;48;51]	4.3 (2.8 to 6.6)	0.4 (0.3 to 0.4)		
Anti-CS Korogwe (PIII[M20]) [N=55;61;52;52;48;57]	8.1 (5.2 to 12.7)	0.3 (0.2 to 0.3)		
Anti-CS Korogwe (PIV[M21]) [N=50;61;48;50;46;54]	7.6 (4.8 to 11.9)	0.3 (0.2 to 0.4)		
Anti-CS Korogwe (PIV[M32]) [N=52;56;44;49;42;48]	4.9 (3 to 7.9)	0.3 (0.2 to 0.3)		
Anti-CS Lambarene (PIII[M20]) [N=32;30;29;44;46;39	8.3 (5.8 to 12.1)	0.3 (0.3 to 0.3)		
Anti-CS Lambarene (PIV[M21]) [N=32;30;29;43;45;35]	7.4 (5 to 10.8)	0.3 (0.2 to 0.3)		
Anti-CS Lambarene (PIV[M32]) [N=29;29;27;38;43;33]	4.1 (2.9 to 5.8)	0.3 (0.2 to 0.3)		
Anti-CS Lilongwe (PIII[M20]) [N=21;17;25;48;46;53]	7.4 (4.7 to 11.5)	0.3 (0.3 to 0.4)		
Anti-CS Lilongwe (PIV[M21]) [N=23;15;24;44;45;51]	8 (5.2 to 12.1)	0.3 (0.2 to 0.4)		
Anti-CS Lilongwe (PIV[M32]) [N=19;16;22;45;46;50]	4.5 (3.1 to 6.6)	0.3 (0.2 to 0.3)		

Anti-CS Nanoro (PIII[M20]) [N=63;60;56;50;69;53]	3.2 (2.1 to 4.7)	0.3 (0.3 to 0.4)		
Anti-CS Nanoro (PIV[M21]) [N=63;60;56;50;68;53]	3.1 (2 to 4.6)	0.3 (0.3 to 0.4)		
Anti-CS Nanoro (PIV[M32]) [N=60;57;51;45;66;51]	2.8 (2 to 4)	0.5 (0.4 to 0.6)		
Anti-CS Siaya (PIII[M20]) [N=46;44;31;40;40;48]	8.9 (5.5 to 14.2)	0.4 (0.3 to 0.5)		
Anti-CS Siaya (PIV[M21]) [N=45;42;28;41;39;45]	8.4 (5.2 to 13.6)	0.4 (0.3 to 0.5)		
Anti-CS Siaya (PIV[M32]) [N=45;40;27;36;36;42]	5.5 (3.3 to 9.2)	0.5 (0.4 to 0.7)		
Anti-CS Manhica (PIII[M20]) [N=0;0;0;45;46;43]	14.7 (10 to 21.5)	0.3 (0.3 to 0.3)		
Anti-CS Manhica (PIV[M21]) [N=0;0;0;36;38;28]	12.3 (7.7 to 19.5)	0.3 (0.2 to 0.3)		
Anti-CS Manhica (PIV[M32]) [N=0;0;0;35;34;30]	6.8 (4 to 11.5)	0.3 (0.3 to 0.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-CS antibody concentrations by site in Agogo, Lilongwe and Siaya

End point title	Anti-CS antibody concentrations by site in Agogo, Lilongwe and Siaya

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 greater than or equal to (≥) 0.5 EL.U/mL.

End point type	Secondary

End point timeframe:

At M44 & SE

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	98	101
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS Agogo (PIII[M44]) [N=47;50;45;0;0;0	27.7 (20.1 to 38.1)	17.9 (13.5 to 23.6)	0.3 (0.2 to 0.3)	0 (0 to 0)
Anti-CS Agogo (SE) [N=47;48;49;32;35;51]	23.2 (16.7 to 32.3)	17.2 (12.7 to 23.3)	0.3 (0.2 to 0.3)	6.1 (3.2 to 11.4)
Anti-CS Lilongwe (PIII[M44]) [N=15;16;19;0;0;0]	30.5 (21.4 to 43.5)	8.5 (4.5 to 15.9)	0.3 (0.2 to 0.3)	0 (0 to 0)
Anti-CS Lilongwe (SE) [N=16;17;23;35;38;42]	26.9 (18.3 to 39.5)	7.2 (4.1 to 12.5)	0.3 (0.3 to 0.3)	10.9 (6.3 to 18.7)
Anti-CS Siaya (PIII[M44]) [N=41;35;22;0;0;0]	41.4 (29.7 to 57.9)	21.2 (14 to 32)	0.5 (0.4 to 0.8)	0 (0 to 0)
Anti-CS Siaya (SE) [N=41;34;26;34;30;38]	27.4 (19.4 to 38.9)	15.8 (10.2 to 24.4)	0.4 (0.3 to 0.6)	10.4 (6.1 to 17.7)

Anti-CS Across (PIV[M44]) [N=103;101;86;0;0;0]	33 (26.9 to 40.3)	16.8 (13.5 to 21)	0.3 (0.3 to 0.4)	0 (0 to 0)
Anti-CS Across (SE) [N=104;99;98;101;103;131]	25.4 (20.6 to 31.2)	14.4 (11.4 to 18.1)	0.3 (0.3 to 0.4)	8.9 (6.5 to 12.3)

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	131		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS Agogo (PIII[M44]) [N=47;50;45;0;0;0	0 (0 to 0)	0 (0 to 0)		
Anti-CS Agogo (SE) [N=47;48;49;32;35;51]	2.1 (1.3 to 3.4)	0.3 (0.2 to 0.4)		
Anti-CS Lilongwe (PIII[M44]) [N=15;16;19;0;0;0]	0 (0 to 0)	0 (0 to 0)		
Anti-CS Lilongwe (SE) [N=16;17;23;35;38;42]	2.8 (1.8 to 4.2)	0.3 (0.2 to 0.3)		
Anti-CS Siaya (PIII[M44]) [N=41;35;22;0;0;0]	0 (0 to 0)	0 (0 to 0)		
Anti-CS Siaya (SE) [N=41;34;26;34;30;38]	3.3 (1.9 to 5.6)	0.4 (0.3 to 0.6)		
Anti-CS Across (PIV[M44]) [N=103;101;86;0;0;0]	0 (0 to 0)	0 (0 to 0)		
Anti-CS Across (SE) [N=104;99;98;101;103;131]	2.6 (2 to 3.4)	0.3 (0.3 to 0.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-CS antibody concentrations in the first 200 subjects in each center, by tertiles

End point title	Anti-CS antibody concentrations in the first 200 subjects in each center, by tertiles[19]

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 greater than or equal to (≥) 0.5 EL.U/mL. Results are 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 Study Month 3

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	R3C (5-17M) Group	R3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	545	639		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS At Month 3 – Tertile 1 (N=181;212)	264.15 (238.2 to 292.9)	78.45 (69.4 to 88.6)		
Anti-CS At Month 3 – Tertile 2 (N=182;214)	613.79 (598.3 to 629.7)	230.68 (224.7 to 236.8)		
Anti-CS At Month 3 – Tertile 3 (N=182;213)	1351.41 (1276.3 to 1431)	592.65 (557.8 to 629.6)		
Anti-CS At Month 3 – Across Tertiles (N=545;639)	603.77 (563.6 to 646.8)	220.9 (204.1 to 239)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of primary case definition (PCD) by tertile

End point title	Time to all episodes of clinical Plasmodium 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, number of CPFMI events reported (n) over period elapsed until all CPFMI events reported occurred for each group (T in year = sum of FU period in years censored at last occurrence of event in each group). RaCPFMI was calculated by tertile of anti-CS response post primary vaccination pooled across sites, on subjects in R3C (5-17M; 6-12W) (or R3C 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 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	R3C (5-17M) Group	C3C (5-17M) Group	R3C (6-12W) Group	C3C (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	565	214	677
Units: n/T				
number (not applicable)				
R3C Tertile 1 & C3C Tertile 1 (N=181;565;212;677	0.68	1.21	1.29	0.93
R3C Tertile 2 & C3C Tertile 2 (N=182;565;214;677)	0.78	1.21	0.7	0.93

R3C Tertile 3 & C3C Tertile 3 (N=182;565;213;677)	1.03	1.21	0.58	0.93

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-CS antibody concentrations in the first 200 subjects in each center, by tertiles

End point title	Anti-CS antibody concentrations in the first 200 subjects in each center, by tertiles[21]

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 greater than or equal to (≥) 0.5 EL.U/mL. Results are 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 Study Month 21

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: Due to the complex study design and multiple time points, the study results were presented across multiple end points, covering the baseline groups.

End point values	R3R (5-17M) Group	R3R (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	465	546		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS At Month 21 – Tertile 1 (N=154;181)	138.15 (123.5 to 154.5)	47.99 (41.2 to 55.9)		
Anti-CS At Month 21 – Tertile 2 (N=156;183)	311.35 (303.4 to 319.6)	194.85 (189.9 to 200)		
Anti-CS At Month 21 – Tertile 3 (N=155;182)	675.24 (632.8 to 720.5)	479.44 (446.8 to 514.5)		
Anti-CS At Month 21 – Across Tertiles (N=465;546)	307.93 (286.2 to 331.3)	165.31 (150 to 182.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all episodes of clinical Plasmodium falciparum malaria infection (CPFMI) of primary case definition (PCD) by tertile

End point title	Time to all episodes of clinical Plasmodium falciparum malaria

	infection (CPFMI) of primary case definition (PCD) by tertile[22]

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, number of CPFMI events reported (n) over period elapsed until all CPFMI events reported occurred for each group (T in year = sum of FU period in years censored at last occurrence of event in each group). 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:

[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: Due to the complex study design and multiple time points, the study results were presented across multiple end points, covering the baseline groups.

End point values	R3R (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group	C3C (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	156	479	420	594
Units: n/T				
number (not applicable)				
R3R Tertile 1 & C3C Tertile 1 (N=154;479;420;594)	0.68	1.21	0.99	0.94
R3R Tertile 2 & C3C Tertile 2 (N=156;479;362;594)	0.68	1.21	0.84	0.94
R3R Tertile 3 & C3C Tertile 3 (N=155;479;276;594)	0.77	1.21	0.64	0.94

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Hepatitis B (anti-HBs) antibody concentrations in the 1st 200 subjects in each center

End point title	Anti-Hepatitis B (anti-HBs) antibody concentrations in the 1st 200 subjects in each center[23]

End point description:

Concentrations, by enzyme-linked immunosorbent assay (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 than or equal to (≥) 10 and 100 mIU/mL, respectively. Results were assessed in the 1st 200 subjects in each center.

End point type	Secondary

End point timeframe:

At baseline & M3

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	526	627	1029	1213
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs (Screening) [N=515;561;1017;1120]	168.6 (142.8 to 199.2)	8.5 (7.7 to 9.4)	166.3 (148 to 186.8)	8.6 (8 to 9.3)
Anti-HBs (PIII[M3]) [N=526;627;1029;1213]	127.5 (108.8 to 149.4)	728.8 (643.6 to 825.2)	81567.7 (75442.7 to 88189.9)	13674.3 (12811.5 to 14595.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody concentrations in the 1st 200 HIV-infected subjects in each center

End point title	Anti-HBs antibody concentrations in the 1st 200 HIV-infected subjects in each center[24]

End point description:

Concentrations, by enzyme-linked immunosorbent assay (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 than or equal to (≥) 10 and 100 mIU/mL, respectively. Results were assessed in the 1st 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 baseline & M3

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	17	5	29	25
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs (Screening) [N=15;5;28;25]	63.6 (19.4 to 208.4)	5 (5 to 5)	98.6 (43.8 to 222)	7.5 (4.8 to 11.6)
Anti-HBs (PIII[M3]) [N=17;5;29;24]	37.1 (9.1 to 151.9)	197.2 (7.7 to 5081.7)	37476.5 (17766 to 79054.9)	1996.2 (561.6 to 7095.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody titers in the first 200 subjects in each center

End point title	Anti-HBs antibody titers in the first 200 subjects in each

End point description:

Concentrations, by enzyme-linked immunosorbent assay (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 than or equal to (≥) 10 and 100 mIU/mL, respectively. Results were assessed in the first 200 subjects in each center.

End point type	Secondary

End point timeframe:

At M20 & M21

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	R3R (5-17M) Group	R3R (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	134		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs (PIII[M20]) (N=95;134)	5068.5 (3711.3 to 6922)	1532.5 (1240.6 to 1893.2)		
Anti-HBs (PIV[M21]) (N=94;48)	95206.4 (72395.4 to 125204.9)	116458.1 (86865.7 to 156131.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Poliomyelitis 1, 2 & 3 antibody titers

End point title	Anti-Poliomyelitis 1, 2 & 3 antibody titers[26]

End point description:

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

End point type	Secondary

End point timeframe:

At baseline & M3

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	C3C (6-12W) Group	RTS,S/AS01 (6-12W) Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	474	931		
Units: Titer				
geometric mean (confidence interval 95%)				
Anti-Polio 1 (Screening) [N=469;928]	43.3 (36.2 to 51.9)	47.4 (41.7 to 53.8)		
Anti-Polio 1(PIII[M3]) [N=464;913]	417.6 (351.4 to 496.2)	334.9 (295.2 to 379.8)		
Anti-Polio 2 (Screening) [N=468;928]	40.3 (34.2 to 47.5)	38.6 (34.6 to 43.2)		
Anti-Polio 2 (PIII[M3]) [N=466;913]	450.8 (393.9 to 516)	372.1 (334.5 to 414)		
Anti-Polio 3 (Screening) [N=474;931]	9.1 (8 to 10.3)	9.4 (8.6 to 10.3)		
Anti-Polio 3 (PIII[M3]) [N=466;913]	95.9 (82 to 112.2)	80 (71 to 90.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with solicited local symptoms post PRI in 1st 200 subjects in each center

End point title	Subjects with solicited local symptoms post PRI in 1st 200 subjects in each center[27]

End point description:

Solicited local symptoms assessed include pain, redness and swelling. “Any” about a specific symptom is defined as incidence of this symptom, regardless of its intensity.

End point type	Secondary

End point timeframe:

Post Primary vaccination (PRI)

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	721	738	1479	1462
Units: Subjects				
Any Pain Dose 1 [N=721;738;1479;1462]	61	215	247	435
Any Redness Dose 1 [N=721;738;1479;1462]	26	89	66	176
Any Swelling Dose 1 [N=721;738;1479;1462]	77	125	140	227
Any Pain Dose 2 [N=708;721;1435;1412]	41	178	179	383
Any Redness Dose 2 [N=708;721;1435;1412]	18	90	26	124
Any Swelling Dose 2 [N=708;721;1435;1412]	50	128	140	228
Any Pain Dose 3 [N=699;710;1407;1378]	22	153	108	345
Any Redness Dose 3 [N=699;710;1407;1378]	13	63	42	113
Any Swelling Dose 3 [N=699;710;1407;1378]	35	111	134	185

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with solicited general symptoms post PRI in 1st 200 subjects in each center

End point title	Subjects with solicited general symptoms post PRI in 1st 200 subjects in each center[28]

End point description:

Solicited general symptoms assessed include Drowsiness, Fever (temperature by axillary route ≥ 37.5°C), Irritability/Fussiness and Loss of appetite. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity or relationship to vaccination.

End point type	Secondary

End point timeframe:

Post Primary vaccination (PRI)

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	721	738	1479	1462
Units: Subjects				
Any Drowsiness Dose 1 [N=721;738;1479;1462]	27	65	91	164
Any Irritability Dose 1 [N=721;738;1479;1462]	41	157	165	370

Any Loss of appetite Dose 1 [N=721;738;1479;1462]	71	52	202	124
Any Temperature Dose 1 [N=721;738;1479;1462]	108	192	385	459
Any Drowsiness Dose 2 [N=708;721;1435;1412]	37	55	99	135
Any Irritability Dose 2 [N=708;721;1435;1412]	45	123	192	289
Any Loss of appetite Dose 2 [N=708;721;1435;1412]	47	43	151	105
Any Temperature Dose 2 [N=708;721;1435;1412]	100	154	503	411
Any Drowsiness Dose 3 [N=699;710;1407;1378]	29	44	97	124
Any Irritability Dose 3 [N=699;710;1407;1378]	27	104	138	287
Any Loss of appetite Dose 3 [N=699;710;1407;1378]	40	45	138	106
Any Temperature Dose 3 [N=699;710;1407;1378]	77	111	457	429

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with solicited local symptoms post Boost in 1st 200 subjects in each center

End point title	Subjects with solicited local symptoms post Boost in 1st 200 subjects in each center

End point description:

Solicited local symptoms assessed include pain, redness and swelling. “Any” about a specific symptom is defined as incidence of this symptom, regardless of its intensity.

End point type	Secondary

End point timeframe:

Post Booster vaccination (BST)

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	641	639	633	608
Units: Subjects				
Any Pain	109	45	41	59
Any Redness	15	13	8	9
Any Swelling	42	35	30	45

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	625	621		

Units: Subjects				
Any Pain	20	25		
Any Redness	12	9		
Any Swelling	28	43		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with solicited general symptoms post Boost in 1st 200 subjects in each center

End point title	Subjects with solicited general symptoms post Boost in 1st 200 subjects in each center

End point description:

Solicited general symptoms assessed include Drowsiness, Fever (temperature by axillary route ≥ 37.5°C), Irritability/Fussiness and Loss of appetite. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity or relationship to vaccination.

End point type	Secondary

End point timeframe:

Post Booster vaccination (BST)

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	641	639	633	608
Units: Subjects				
Any Drowsiness	55	22	21	33
Any Irritability	63	25	18	46
Any Loss of appetite	66	27	21	45
Any Temperature	233	70	45	152

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	625	621		
Units: Subjects				
Any Drowsiness	19	15		
Any Irritability	23	23		
Any Loss of appetite	27	18		
Any Temperature	52	58		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with seizures by diagnostic certainty level

End point title	Subjects with seizures by diagnostic certainty level

End point description:

End point type	Secondary

End point timeframe:

Post BST by diagnostic certainty level

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2447	2472	2473	1825
Units: Subjects				
Diagnostic certainty Level 1	1	1	0	1
Diagnostic certainty Level 2	5	2	1	3
Diagnostic certainty Level 3	0	0	0	0
Diagnostic certainty Level 4	1	0	0	0
Diagnostic certainty Level 5	1	1	0	0

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1837	1827		
Units: Subjects				
Diagnostic certainty Level 1	0	0		
Diagnostic certainty Level 2	0	1		
Diagnostic certainty Level 3	0	0		
Diagnostic certainty Level 4	0	0		
Diagnostic certainty Level 5	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with mucocutaneous changes reported (all levels) in 1st 200 subjects in each centre

End point title	Subjects with mucocutaneous changes reported (all levels) in 1st 200 subjects in each centre[29]

End point description:

End point type	Secondary

End point timeframe:

Post Booster vaccination (BST)

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	R3R (6-12W) Group	R3C (6-12W) Group	C3C (6-12W) Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	605	617	614	
Units: Subjects				
Cutaneous and/or mucosal change	64	47	59	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with meningitis and encephalitis SAEs

End point title	Subjects with meningitis and encephalitis SAEs

End point description:

End point type	Secondary

End point timeframe:

At Month0-Study End (SE)

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2976	2972	2974	2180
Units: Subjects				
Any Meningitis and Encephalitis	15	12	5	7

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2178	2179		
Units: Subjects				
Any Meningitis and Encephalitis	8	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with meningitis and encephalitis SAEs

End point title	Subjects with meningitis and encephalitis SAEs

End point description:

End point type	Secondary

End point timeframe:

Booster (BST) to Study End (SE)

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2681	2719	2702	1966
Units: Subjects				
Any Meningitis and Encephalitis	4	4	0	0

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1996	1976		
Units: Subjects				
Any Meningitis and Encephalitis	2	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with potential immune-mediated disorders (pIMDs)

End point title	Subjects with potential immune-mediated disorders (pIMDs)

End point description:

End point type	Secondary

End point timeframe:

From Month0-Study End (SE)

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2976	2972	2974	2180
Units: Subjects				
Any pIMD(s)	5	1	4	3

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2178	2179		
Units: Subjects				
Any pIMD(s)	1	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with unsolicited adverse events (AEs)

End point title	Subjects with unsolicited adverse events (AEs)[30]

End point description:

End point type	Secondary

End point timeframe:

Post PRI in 1st 200 subjects in each center

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	721	738	1479	1462
Units: Subjects				
Any AE(s)	626	600	1273	1161

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with unsolicited AEs related or leading to vaccine withdrawal

End point title	Subjects with unsolicited AEs related or leading to vaccine withdrawal[31]

End point description:

End point type	Secondary

End point timeframe:

Post PRI in 1st 200 subjects in each center

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2003	2179	3997	4358
Units: Subjects				
Any AE(s)	72	231	399	578

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with unsolicited AEs

End point title	Subjects with unsolicited AEs

End point description:

End point type	Secondary

End point timeframe:

Post Booster (BST) in 1st 200 in each center

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	641	639	633	608
Units: Subjects				
Any AE(s)	232	205	215	231

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	625	621		
Units: Subjects				
Any AE(s)	239	240		

Statistical analyses

No statistical analyses for this end point

Secondary: 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	Subjects with unsolicited AEs related to or leading to vaccination withdrawal in the low-weight (LW) and very low weight (VLW) category[32]

End point description:

End point type	Secondary

End point timeframe:

Post Pri among 1st 200 subjects in each center in HIV infected subjects

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	364	126	695	221
Units: Subjects				
Any AE(s), in LW (N=364;126;695;221)	21	17	68	38
Any AE(s), in VLW (N=97;67;207;147	6	10	27	24

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with unsolicited AEs related to or leading to vaccination withdrawal

End point title	Subjects with unsolicited AEs related to or leading to vaccination withdrawal

End point description:

End point type	Secondary

End point timeframe:

Post Pri and Post BST among 1st 200 subjects in each center in HIV infected subjects

End point values	RTS,S/AS01 Group	R3R Group	R3C Group	C3C 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: Subjects				
Any AE(s) post PRI (N=84;0;0;41)	13	0	0	3
Any AE(s) post BST (N=0;33;35;28)	0	2	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: 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	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:

End point type	Secondary

End point timeframe:

Post Booster (BST) among 1st 200 in each center in HIV infected among 1st 200 in each center

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	273	297	293	230
Units: Subjects				
Any AE(s) in LW (N=273;297;293;230;208;195)	4	1	0	2
Any AE(s) in VLW (N=48;49;59;45;45;68)	5	0	0	2

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	208	195		
Units: Subjects				
Any AE(s) in LW (N=273;297;293;230;208;195)	0	1		
Any AE(s) in VLW (N=48;49;59;45;45;68)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with serious adverse events (SAEs)

End point title	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 Month0-Month 14

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2974	2179	5949	4358
Units: Subjects				
Any SAE(s)	634	419	1040	782

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with serious adverse events (SAEs)

End point title	Subjects with serious adverse events (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:

30 days post primary vaccination (PRI)

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: Due to the complex study design and number of time points covered, the results were presented over multiple end points.

End point values	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2974	2179	5949	4358
Units: Subjects				
Any SAE(s)	181	96	312	192

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs

End point title	Subjects with 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.

End point type	Secondary

End point timeframe:

From Month 0 to Month 20

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	2974	2179	5949	4358
Units: Subjects				
Any SAE(s), M0-M20	676	503	1108	959

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs

End point title	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:

From Booster at Month 20 to Study end

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2681	2719	2702	1966
Units: Subjects				
Any SAE(s)	276	316	287	180

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1996	1976		
Units: Subjects				
Any SAE(s)	193	201		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs

End point title	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:

From Month 0 to Study End

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2976	2972	2974	2180
Units: Subjects				
Any SAE(s), M0-Study End	720	752	846	580

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2178	2179		
Units: Subjects				
Any SAE(s), M0-Study End	602	619		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs

End point title	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:

30 days post Booster

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2447	2472	2473	1825
Units: Subjects				
Any SAE(s), 30 Days post Booster	34	22	27	19

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1837	1827		
Units: Subjects				
Any SAE(s), 30 Days post Booster	19	20		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs

End point title	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:

From Month0-Month 20 (Booster),from Month20-Study End (SE), and from Month0-Study End

End point values	R3R Group	R3C Group	C3C Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	51	54	48	
Units: Subjects				
Any SAE(s), M0-M20 (N=51;54;48	43	39	36	
Any SAE(s), M20-SE (N=38;42;32)	19	19	16	
Any SAE(s), M0-SE (N=51;54;48)	47	46	42	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs in LW at baseline

End point title	Subjects with SAEs in LW at baseline[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.

End point type	Secondary

End point timeframe:

Month0-Month20

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	364	126	695	221
Units: Subjects				
Any SAE(s)	89	38	174	63

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs with LW

End point title	Subjects with SAEs with LW

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-Study End in Low Weight at Booster

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	277	304	297	232
Units: Subjects				
Any SAE(s)	32	40	38	34

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	211	195		
Units: Subjects				
Any SAE(s)	21	24		

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs in VLW at baseline

End point title	Subjects with SAEs in VLW at baseline[37]

End point description:

The SAEs were reported in subjects of very low weight (VLW) at baseline

End point type	Secondary

End point timeframe:

From Month 0-Month20

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	C3C (5-17M) Group	C3C (6-12W) Group	RTS,S/AS01 (5-17M)	RTS,S/AS01 (6-12W) Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	97	67	207	147
Units: Subjects				
Any SAE(s)	28	17	55	48

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with SAEs

End point title	Subjects with SAEs

End point description:

End point type	Secondary

End point timeframe:

Booster-Study End in VLW at Booster

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	50	60	48
Units: Subjects				
Any SAE(s)	5	8	11	6

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	68		
Units: Subjects				
Any SAE(s)	9	15		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number (%) of subjects with fatal outcomes, by gender

End point title	Number (%) of subjects with fatal outcomes, by gender

End point description:

Mortality was presented as overall mortality (OM up to M20 and up to study end), mortality due to severe malaria as per secondary case definition(SM SCD), cerebral malaria as per secondary case definition (CM SCD), meningitis (Men), fatal all-cause traumas (FAT) and fatal malaria (FM). SCD= Plasmodium falciparum malaria > 5000 parasites/mcLand 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	Other pre-specified

End point timeframe:

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

End point values	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group	R3R (6-12W) Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2976	2972	2974	2180
Units: Subjects				
OM (M0-M20) Females	27	20	14	20
OM (M0-SE) Females	35	32	17	27
OM (M0-M20) Males	19	8	19	20
OM (M0-SE) Males	26	19	29	24
SM SCD, All, Females	75	107	100	57
SM SCD, All, Males	87	115	134	78
SM SCD, Fatal, Females	4	4	2	2
SM SCD, Fatal, Males	3	4	2	2
CM SCD, All, Females	16	14	7	1
CM SCD, All, Males	10	14	9	9
CM SCD, Fatal, Females	3	4	2	1
CM SCD, Fatal, Males	2	1	0	1
FAT, Females	3	4	1	1
FAT, Males	4	1	3	1
FM, Females	9	8	4	5
FM, Males	4	9	8	3
Men, All, Females	5	5	1	2
Men, All, Males	6	5	2	3
Men, Fatal, Females	2	3	0	0
Men, Fatal, Males	2	0	1	1

End point values	R3C (6-12W) Group	C3C (6-12W) Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2139	2179		
Units: Subjects				
OM (M0-M20) Females	24	13		
OM (M0-SE) Females	29	16		
OM (M0-M20) Males	29	21		
OM (M0-SE) Males	26	26		
SM SCD, All, Females	49	75		
SM SCD, All, Males	80	79		
SM SCD, Fatal, Females	0	0		
SM SCD, Fatal, Males	2	2		
CM SCD, All, Females	5	7		
CM SCD, All, Males	7	3		
CM SCD, Fatal, Females	0	0		

CM SCD, Fatal, Males	1	0		
FAT, Females	1	2		
FAT, Males	2	0		
FM, Females	4	3		
FM, Males	8	3		
Men, All, Females	2	3		
Men, All, Males	5	3		
Men, Fatal, Females	0	1		
Men, Fatal, Males	1	2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited and unsolicited AEs: respectively 7-day (D) (D0-6) & 30-D (D0-29) follow-up (FU) periods post vaccination (PRI or BST); SAEs: Month [M] 0 to study end (median FU = 48M in 5-17M subjects & 38M for 6-12W subjects).

Adverse event reporting additional description:

In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'. Occurrence of reported AEs (all/related) was not available & is encoded as equal to number of subjects affected.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	R3R (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) according to a Month 0, 1 and 2 followed by a booster dose of the same RTS,S/AS01 vaccine administered at Month 20. The RTS,S/AS01 vaccine was administered intramuscularly in the left deltoid.

Reporting group title	R3C (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) according to a Month 0, 1 and 2 followed by a booster dose of Menjugate (or MenC vaccine) administered at Month 20. The RTS,S/AS01 and MenC vaccines were administered intramuscularly in the left deltoid.

Reporting group title	C3C (5-17M) Group

Reporting group description:

Subjects in this group, aged 5 to 17 months at first vaccination, received a 3-dose primary vaccination course of Verorab (also referred to as Rabies vaccine) according to a Month 0, 1 and 2 followed by a booster dose of the Menjugate vaccine (MenC) administered at Month 20. The Rabies and MenC vaccines were administered intramuscularly in the left deltoid.

Reporting group title	R3R (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of the same RTS,S/AS01 vaccine co-administered with OPV at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the primary RTS,S/AS01 vaccine doses were injected in the anterolateral left thigh and the booster dose into the left deltoid; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Reporting group title	R3C (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049, vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of dose of Menjugate (or MenC vaccine) co-administered with OPV vaccine at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the primary RTS,S/AS01 vaccine doses were injected in the anterolateral left thigh; the MenC vaccine was injected in the left thigh for children < 1 year of age and into the left deltoid in children > 1 year of age; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Reporting group title	RTS,S/AS01 (5-17M) Group

Reporting group description:

This group results from the pooling of the R3R (5-17M) and R3C (5-17M) groups and include subjects who received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049) according to a Month 0, 1 and 2 schedule followed by, at Month 20, either a booster dose of the RTS,S/AS01 vaccine or a dose of Menjugate (or MenC). Refer to the respective descriptions for the R3R (5-17M) and R3C (5-17M) groups for details on routes of vaccination.

Reporting group title	C3C (6-12W) Group

Reporting group description:

Subjects in this group, aged 6 to 12 weeks at first vaccination, received a 3-dose primary vaccination course of Menjugate (or MenC vaccine) co-administered with Polio Sabin (or OPV vaccine) and Tritanrix HepB/Hib (or DTPwHepB/Hib vaccine) (reconstituted from Tritanrix HepB and Hiberix vaccines) according to a Month 0, 1 and 2 followed by a booster dose of dose of MenC vaccine co-administered with OPV vaccine at Month 20. All vaccines were administered intramuscularly, except the OPV vaccine given orally; the MenC vaccine was injected in the left thigh for children < 1 year of age and into the left deltoid in children > 1 year of age; the DTPwHepB/Hib vaccine was injected in the anterolateral right thigh.

Reporting group title	RTS,S/AS01 (6-12W) Group

Reporting group description:

This group results from the pooling of the R3R (6-12W) and R3C (6-12W) groups and include subjects who received a 3-dose primary vaccination course of the RTS,S/AS01 vaccine (also referred to as RTS,S or GSK 257049) co-administered with Polio Sabin (or OPV) and Tritanrix HepB/Hib (or DTPwHepB/Hib) according to a Month 0, 1 and 2 schedule followed by, at Month 20, either a booster dose of the RTS,S/AS01 and OPV vaccines or a booster dose of Menjugate (or MenC) and OPV vaccines. Refer to the respective descriptions for the R3R (6-12W) and R3C (6-12W) groups for details on routes of vaccination.

Serious adverse events	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group
Total subjects affected by serious adverse events			
subjects affected / exposed	720 / 2976 (24.19%)	752 / 2972 (25.30%)	846 / 2974 (28.45%)
number of deaths (all causes)	61	51	46
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute promyelocytic leukaemia			
subjects affected / exposed[1]	0 / 2976 (0.00%)	0 / 2972 (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
Brain neoplasm			
subjects affected / exposed[2]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed[3]	0 / 2976 (0.00%)	0 / 2972 (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

Langerhans' cell histiocytosis			
subjects affected / exposed[4]	0 / 2976 (0.00%)	0 / 2972 (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[5]	2 / 2976 (0.07%)	0 / 2972 (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
Hypovolaemic shock			
subjects affected / exposed[6]	0 / 2976 (0.00%)	0 / 2972 (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
Shock			
subjects affected / exposed[7]	0 / 2976 (0.00%)	3 / 2972 (0.10%)	5 / 2974 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
General disorders and administration site conditions			
Death			
subjects affected / exposed[8]	3 / 2976 (0.10%)	1 / 2972 (0.03%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
Drowning			
subjects affected / exposed[9]	3 / 2976 (0.10%)	2 / 2972 (0.07%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 3
Generalised oedema			
subjects affected / exposed[10]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Hernia			
subjects affected / exposed[11]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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

Hypothermia			
subjects affected / exposed[12]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Injection site reaction			
subjects affected / exposed[13]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Pyrexia			
subjects affected / exposed[14]	18 / 2976 (0.60%)	10 / 2972 (0.34%)	16 / 2974 (0.54%)
occurrences causally related to treatment / all	1 / 18	2 / 10	0 / 16
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed[15]	0 / 2976 (0.00%)	0 / 2972 (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
Anaphylactic reaction			
subjects affected / exposed[16]	0 / 2976 (0.00%)	0 / 2972 (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
Hypersensitivity			
subjects affected / exposed[17]	0 / 2976 (0.00%)	3 / 2972 (0.10%)	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
Social circumstances			
Child abuse			
subjects affected / exposed[18]	1 / 2976 (0.03%)	0 / 2972 (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[19]	2 / 2976 (0.07%)	0 / 2972 (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

Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed[20]	0 / 2976 (0.00%)	0 / 2972 (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
Respiratory, thoracic and mediastinal disorders			
Apnoeic attack			
subjects affected / exposed[21]	0 / 2976 (0.00%)	0 / 2972 (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
Asphyxia			
subjects affected / exposed[22]	1 / 2976 (0.03%)	0 / 2972 (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 / 1	0 / 0	0 / 1
Aspiration			
subjects affected / exposed[23]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Asthma			
subjects affected / exposed[24]	9 / 2976 (0.30%)	6 / 2972 (0.20%)	8 / 2974 (0.27%)
occurrences causally related to treatment / all	0 / 9	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed[25]	0 / 2976 (0.00%)	0 / 2972 (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
Bronchospasm			
subjects affected / exposed[26]	2 / 2976 (0.07%)	0 / 2972 (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
Cough			

subjects affected / exposed[27]	1 / 2976 (0.03%)	0 / 2972 (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
Epistaxis			
subjects affected / exposed[28]	0 / 2976 (0.00%)	0 / 2972 (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
Interstitial lung disease			
subjects affected / exposed[29]	0 / 2976 (0.00%)	0 / 2972 (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
Obstructive airways disorder			
subjects affected / exposed[30]	0 / 2976 (0.00%)	0 / 2972 (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[31]	1 / 2976 (0.03%)	0 / 2972 (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[32]	7 / 2976 (0.24%)	1 / 2972 (0.03%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Pneumonitis			
subjects affected / exposed[33]	0 / 2976 (0.00%)	0 / 2972 (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
Pulmonary oedema			
subjects affected / exposed[34]	1 / 2976 (0.03%)	0 / 2972 (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 / 1	0 / 0	0 / 0
Respiratory acidosis			

subjects affected / exposed[35]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 arrest			
subjects affected / exposed[36]	0 / 2976 (0.00%)	0 / 2972 (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[37]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Psychiatric disorders			
Neurodevelopmental disorder			
subjects affected / exposed[38]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed[39]	0 / 2976 (0.00%)	0 / 2972 (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[40]	0 / 2976 (0.00%)	0 / 2972 (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[41]	1 / 2976 (0.03%)	0 / 2972 (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[42]	0 / 2976 (0.00%)	0 / 2972 (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[43]	3 / 2976 (0.10%)	1 / 2972 (0.03%)	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
Burns first degree			
subjects affected / exposed[44]	2 / 2976 (0.07%)	2 / 2972 (0.07%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed[45]	1 / 2976 (0.03%)	5 / 2972 (0.17%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chemical injury			
subjects affected / exposed[46]	1 / 2976 (0.03%)	0 / 2972 (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[47]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	7 / 2974 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed[48]	0 / 2976 (0.00%)	0 / 2972 (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[49]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Disinfectant poisoning			
subjects affected / exposed[50]	0 / 2976 (0.00%)	0 / 2972 (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
Exposure to toxic agent			

subjects affected / exposed[51]	1 / 2976 (0.03%)	0 / 2972 (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[52]	1 / 2976 (0.03%)	0 / 2972 (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[53]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Femur fracture			
subjects affected / exposed[54]	3 / 2976 (0.10%)	0 / 2972 (0.00%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed[55]	4 / 2976 (0.13%)	1 / 2972 (0.03%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body aspiration			
subjects affected / exposed[56]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Fractured skull depressed			
subjects affected / exposed[57]	1 / 2976 (0.03%)	0 / 2972 (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[58]	0 / 2976 (0.00%)	0 / 2972 (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
Head injury			

subjects affected / exposed[59]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Herbal toxicity			
subjects affected / exposed[60]	2 / 2976 (0.07%)	3 / 2972 (0.10%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 1
Human bite			
subjects affected / exposed[61]	0 / 2976 (0.00%)	0 / 2972 (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[62]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Joint injury			
subjects affected / exposed[63]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Laceration			
subjects affected / exposed[64]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed[65]	0 / 2976 (0.00%)	0 / 2972 (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[66]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Penis injury			

subjects affected / exposed[67]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Petroleum distillate poisoning			
subjects affected / exposed[68]	2 / 2976 (0.07%)	2 / 2972 (0.07%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis chemical			
subjects affected / exposed[69]	4 / 2976 (0.13%)	1 / 2972 (0.03%)	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
Poisoning			
subjects affected / exposed[70]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Pulmonary contusion			
subjects affected / exposed[71]	1 / 2976 (0.03%)	0 / 2972 (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[72]	1 / 2976 (0.03%)	0 / 2972 (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 / 1	0 / 0	0 / 1
Sciatic nerve injury			
subjects affected / exposed[73]	0 / 2976 (0.00%)	0 / 2972 (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[74]	0 / 2976 (0.00%)	0 / 2972 (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[75]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Soft tissue injury			
subjects affected / exposed[76]	2 / 2976 (0.07%)	0 / 2972 (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
Thermal burn			
subjects affected / exposed[77]	15 / 2976 (0.50%)	10 / 2972 (0.34%)	15 / 2974 (0.50%)
occurrences causally related to treatment / all	0 / 15	0 / 10	0 / 15
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed[78]	1 / 2976 (0.03%)	0 / 2972 (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
Vaccination failure			
subjects affected / exposed[79]	0 / 2976 (0.00%)	0 / 2972 (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			
subjects affected / exposed[80]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Wrist fracture			
subjects affected / exposed[81]	0 / 2976 (0.00%)	0 / 2972 (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
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed[82]	1 / 2976 (0.03%)	0 / 2972 (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 / 1	0 / 0	0 / 0
Cerebral palsy			

subjects affected / exposed[83]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Choledochal cyst			
subjects affected / exposed[84]	0 / 2976 (0.00%)	0 / 2972 (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[85]	0 / 2976 (0.00%)	0 / 2972 (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[86]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Fallot’s tetralogy			
subjects affected / exposed[87]	0 / 2976 (0.00%)	0 / 2972 (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[88]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	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
Hydrocele			
subjects affected / exposed[89]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Phimosis			
subjects affected / exposed[90]	1 / 2976 (0.03%)	0 / 2972 (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
Sickle cell anaemia			

subjects affected / exposed[91]	1 / 2976 (0.03%)	4 / 2972 (0.13%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis			
subjects affected / exposed[92]	4 / 2976 (0.13%)	4 / 2972 (0.13%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Trisomy 21			
subjects affected / exposed[93]	0 / 2976 (0.00%)	0 / 2972 (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[94]	0 / 2976 (0.00%)	0 / 2972 (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[95]	0 / 2976 (0.00%)	0 / 2972 (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[96]	0 / 2976 (0.00%)	0 / 2972 (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[97]	1 / 2976 (0.03%)	0 / 2972 (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[98]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Pericardial effusion			

subjects affected / exposed[99]	0 / 2976 (0.00%)	0 / 2972 (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
Nervous system disorders			
Arachnoid cyst			
subjects affected / exposed[100]	0 / 2976 (0.00%)	0 / 2972 (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[101]	0 / 2976 (0.00%)	0 / 2972 (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[102]	1 / 2976 (0.03%)	0 / 2972 (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[103]	57 / 2976 (1.92%)	45 / 2972 (1.51%)	58 / 2974 (1.95%)
occurrences causally related to treatment / all	0 / 57	0 / 45	0 / 58
deaths causally related to treatment / all	0 / 8	0 / 8	0 / 10
Depressed level of consciousness			
subjects affected / exposed[104]	0 / 2976 (0.00%)	0 / 2972 (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[105]	0 / 2976 (0.00%)	0 / 2972 (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
Encephalopathy			
subjects affected / exposed[106]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Epilepsy			

subjects affected / exposed[107]	3 / 2976 (0.10%)	10 / 2972 (0.34%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 10	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed[108]	159 / 2976 (5.34%)	184 / 2972 (6.19%)	164 / 2974 (5.51%)
occurrences causally related to treatment / all	6 / 159	1 / 184	1 / 164
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 3
Haemorrhage intracranial			
subjects affected / exposed[109]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Hemiparesis			
subjects affected / exposed[110]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Hemiplegia			
subjects affected / exposed[111]	0 / 2976 (0.00%)	0 / 2972 (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
Hydrocephalus			
subjects affected / exposed[112]	1 / 2976 (0.03%)	0 / 2972 (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[113]	0 / 2976 (0.00%)	0 / 2972 (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[114]	0 / 2976 (0.00%)	0 / 2972 (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
Mental retardation			

subjects affected / exposed[115]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Metabolic encephalopathy			
subjects affected / exposed[116]	0 / 2976 (0.00%)	0 / 2972 (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
Monoparesis			
subjects affected / exposed[117]	0 / 2976 (0.00%)	0 / 2972 (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
Myoclonus			
subjects affected / exposed[118]	0 / 2976 (0.00%)	0 / 2972 (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[119]	0 / 2976 (0.00%)	0 / 2972 (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
Speech disorder developmental			
subjects affected / exposed[120]	1 / 2976 (0.03%)	0 / 2972 (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
Uraemic encephalopathy			
subjects affected / exposed[121]	0 / 2976 (0.00%)	0 / 2972 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed[122]	126 / 2976 (4.23%)	150 / 2972 (5.05%)	197 / 2974 (6.62%)
occurrences causally related to treatment / all	0 / 126	0 / 150	0 / 197
deaths causally related to treatment / all	0 / 10	0 / 7	0 / 12
Dislocation of vertebra			

subjects affected / exposed[123]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed[124]	1 / 2976 (0.03%)	0 / 2972 (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 / 1	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed[125]	0 / 2976 (0.00%)	0 / 2972 (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
Haemolytic anaemia			
subjects affected / exposed[126]	0 / 2976 (0.00%)	0 / 2972 (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
Hypochromic anaemia			
subjects affected / exposed[127]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Intravascular haemolysis			
subjects affected / exposed[128]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemoid reaction			
subjects affected / exposed[129]	0 / 2976 (0.00%)	0 / 2972 (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[130]	4 / 2976 (0.13%)	3 / 2972 (0.10%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed[131]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pancytopenia			
subjects affected / exposed[132]	0 / 2976 (0.00%)	0 / 2972 (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[133]	0 / 2976 (0.00%)	0 / 2972 (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
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed[134]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Hearing impaired			
subjects affected / exposed[135]	1 / 2976 (0.03%)	0 / 2972 (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[136]	0 / 2976 (0.00%)	0 / 2972 (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
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed[137]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Colitis			
subjects affected / exposed[138]	0 / 2976 (0.00%)	0 / 2972 (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[139]	0 / 2976 (0.00%)	0 / 2972 (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[140]	10 / 2976 (0.34%)	18 / 2972 (0.61%)	15 / 2974 (0.50%)
occurrences causally related to treatment / all	0 / 10	0 / 18	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed[141]	1 / 2976 (0.03%)	0 / 2972 (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
Gastritis			
subjects affected / exposed[142]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed[143]	0 / 2976 (0.00%)	0 / 2972 (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[144]	0 / 2976 (0.00%)	0 / 2972 (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[145]	1 / 2976 (0.03%)	0 / 2972 (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[146]	0 / 2976 (0.00%)	0 / 2972 (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[147]	0 / 2976 (0.00%)	0 / 2972 (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[148]	0 / 2976 (0.00%)	0 / 2972 (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
Intestinal obstruction			
subjects affected / exposed[149]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Intestinal perforation			
subjects affected / exposed[150]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Intussusception			
subjects affected / exposed[151]	0 / 2976 (0.00%)	0 / 2972 (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[152]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 polyp			
subjects affected / exposed[153]	0 / 2976 (0.00%)	0 / 2972 (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
Rectal prolapse			
subjects affected / exposed[154]	1 / 2976 (0.03%)	0 / 2972 (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
Stomatitis			

subjects affected / exposed[155]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Stress ulcer			
subjects affected / exposed[156]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Umbilical hernia			
subjects affected / exposed[157]	0 / 2976 (0.00%)	0 / 2972 (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[158]	1 / 2976 (0.03%)	0 / 2972 (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[159]	1 / 2976 (0.03%)	0 / 2972 (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[160]	0 / 2976 (0.00%)	0 / 2972 (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[161]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Drug hypersensitivity			
subjects affected / exposed[162]	0 / 2976 (0.00%)	0 / 2972 (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
Hepatitis			

subjects affected / exposed[163]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed[164]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 toxic			
subjects affected / exposed[165]	1 / 2976 (0.03%)	0 / 2972 (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
Immune reconstitution inflammatory syndrome			
subjects affected / exposed[166]	0 / 2976 (0.00%)	0 / 2972 (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
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed[167]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Dermatitis allergic			
subjects affected / exposed[168]	0 / 2976 (0.00%)	0 / 2972 (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[169]	0 / 2976 (0.00%)	0 / 2972 (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[170]	0 / 2976 (0.00%)	0 / 2972 (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
Erythema multiforme			

subjects affected / exposed[171]	1 / 2976 (0.03%)	0 / 2972 (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[172]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Rash maculo-papular			
subjects affected / exposed[173]	1 / 2976 (0.03%)	0 / 2972 (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[174]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Skin lesion			
subjects affected / exposed[175]	0 / 2976 (0.00%)	0 / 2972 (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 / 1
Stevens-Johnson syndrome			
subjects affected / exposed[176]	0 / 2976 (0.00%)	0 / 2972 (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[177]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Vitiligo			
subjects affected / exposed[178]	0 / 2976 (0.00%)	0 / 2972 (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[179]	0 / 2976 (0.00%)	0 / 2972 (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
Glomerulonephritis acute			
subjects affected / exposed[180]	0 / 2976 (0.00%)	0 / 2972 (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[181]	0 / 2976 (0.00%)	0 / 2972 (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[182]	0 / 2976 (0.00%)	0 / 2972 (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[183]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Renal failure acute			
subjects affected / exposed[184]	0 / 2976 (0.00%)	0 / 2972 (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[185]	0 / 2976 (0.00%)	0 / 2972 (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[186]	0 / 2976 (0.00%)	0 / 2972 (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[187]	2 / 2976 (0.07%)	0 / 2972 (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[188]	0 / 2976 (0.00%)	0 / 2972 (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
Dactylitis			
subjects affected / exposed[189]	0 / 2976 (0.00%)	0 / 2972 (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[190]	1 / 2976 (0.03%)	0 / 2972 (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
Myositis			
subjects affected / exposed[191]	2 / 2976 (0.07%)	1 / 2972 (0.03%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed[192]	0 / 2976 (0.00%)	0 / 2972 (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
Rickets			
subjects affected / exposed[193]	0 / 2976 (0.00%)	0 / 2972 (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
Torticollis			
subjects affected / exposed[194]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Infections and infestations			
Abscess			

subjects affected / exposed[195]	7 / 2976 (0.24%)	7 / 2972 (0.24%)	5 / 2974 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			
subjects affected / exposed[196]	1 / 2976 (0.03%)	0 / 2972 (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[197]	1 / 2976 (0.03%)	0 / 2972 (0.00%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed[198]	0 / 2976 (0.00%)	0 / 2972 (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[199]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	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
AIDS dementia complex			
subjects affected / exposed[200]	0 / 2976 (0.00%)	0 / 2972 (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[201]	1 / 2976 (0.03%)	0 / 2972 (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[202]	2 / 2976 (0.07%)	7 / 2972 (0.24%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascariasis			

subjects affected / exposed[203]	0 / 2976 (0.00%)	0 / 2972 (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[204]	0 / 2976 (0.00%)	0 / 2972 (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[205]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed[206]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Bone tuberculosis			
subjects affected / exposed[207]	0 / 2976 (0.00%)	0 / 2972 (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[208]	0 / 2976 (0.00%)	0 / 2972 (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[209]	0 / 2976 (0.00%)	0 / 2972 (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[210]	25 / 2976 (0.84%)	13 / 2972 (0.44%)	18 / 2974 (0.61%)
occurrences causally related to treatment / all	0 / 25	0 / 13	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed[211]	13 / 2976 (0.44%)	15 / 2972 (0.50%)	21 / 2974 (0.71%)
occurrences causally related to treatment / all	0 / 13	0 / 15	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchopneumonia			
subjects affected / exposed[212]	33 / 2976 (1.11%)	35 / 2972 (1.18%)	40 / 2974 (1.34%)
occurrences causally related to treatment / all	0 / 33	0 / 35	0 / 40
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 1
Bullous impetigo			
subjects affected / exposed[213]	1 / 2976 (0.03%)	0 / 2972 (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[214]	1 / 2976 (0.03%)	0 / 2972 (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[215]	1 / 2976 (0.03%)	2 / 2972 (0.07%)	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
Candida infection			
subjects affected / exposed[216]	0 / 2976 (0.00%)	0 / 2972 (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[217]	8 / 2976 (0.27%)	7 / 2972 (0.24%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis of male external genital organ			
subjects affected / exposed[218]	1 / 2976 (0.03%)	0 / 2972 (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[219]	1 / 2976 (0.03%)	0 / 2972 (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[220]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Central nervous system viral infection			
subjects affected / exposed[221]	0 / 2976 (0.00%)	0 / 2972 (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[222]	4 / 2976 (0.13%)	4 / 2972 (0.13%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 0
Cholera			
subjects affected / exposed[223]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Conjunctivitis			
subjects affected / exposed[224]	2 / 2976 (0.07%)	4 / 2972 (0.13%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed[225]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Croup infectious			
subjects affected / exposed[226]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Dermatitis infected			

subjects affected / exposed[227]	0 / 2976 (0.00%)	0 / 2972 (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[228]	1 / 2976 (0.03%)	0 / 2972 (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 / 1
Dysentery			
subjects affected / exposed[229]	11 / 2976 (0.37%)	13 / 2972 (0.44%)	9 / 2974 (0.30%)
occurrences causally related to treatment / all	0 / 11	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Eczema infected			
subjects affected / exposed[230]	0 / 2976 (0.00%)	0 / 2972 (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[231]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Encephalitis			
subjects affected / exposed[232]	4 / 2976 (0.13%)	1 / 2972 (0.03%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Encephalitis viral			
subjects affected / exposed[233]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Encephalomyelitis			
subjects affected / exposed[234]	1 / 2976 (0.03%)	0 / 2972 (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[235]	1 / 2976 (0.03%)	0 / 2972 (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
Erysipelas			
subjects affected / exposed[236]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Escherichia sepsis			
subjects affected / exposed[237]	0 / 2976 (0.00%)	0 / 2972 (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
Escherichia urinary tract infection			
subjects affected / exposed[238]	1 / 2976 (0.03%)	0 / 2972 (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
Exanthema subitum			
subjects affected / exposed[239]	0 / 2976 (0.00%)	0 / 2972 (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
Febrile infection			
subjects affected / exposed[240]	0 / 2976 (0.00%)	0 / 2972 (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[241]	1 / 2976 (0.03%)	0 / 2972 (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[242]	153 / 2976 (5.14%)	148 / 2972 (4.98%)	177 / 2974 (5.95%)
occurrences causally related to treatment / all	0 / 153	0 / 148	0 / 177
deaths causally related to treatment / all	0 / 14	0 / 7	0 / 8
Gastroenteritis Escherichia coli			

subjects affected / exposed[243]	0 / 2976 (0.00%)	0 / 2972 (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[244]	2 / 2976 (0.07%)	3 / 2972 (0.10%)	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
Gastroenteritis shigella			
subjects affected / exposed[245]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Gastroenteritis viral			
subjects affected / exposed[246]	0 / 2976 (0.00%)	0 / 2972 (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[247]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	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
Giardiasis			
subjects affected / exposed[248]	0 / 2976 (0.00%)	0 / 2972 (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
Gingivitis			
subjects affected / exposed[249]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Groin abscess			
subjects affected / exposed[250]	1 / 2976 (0.03%)	0 / 2972 (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[251]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Helminthic infection			
subjects affected / exposed[252]	2 / 2976 (0.07%)	8 / 2972 (0.27%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed[253]	2 / 2976 (0.07%)	2 / 2972 (0.07%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis B			
subjects affected / exposed[254]	0 / 2976 (0.00%)	0 / 2972 (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
Hepatitis infectious			
subjects affected / exposed[255]	0 / 2976 (0.00%)	0 / 2972 (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 associated nephropathy			
subjects affected / exposed[256]	0 / 2976 (0.00%)	0 / 2972 (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			
subjects affected / exposed[257]	22 / 2976 (0.74%)	19 / 2972 (0.64%)	18 / 2974 (0.61%)
occurrences causally related to treatment / all	0 / 22	0 / 19	0 / 18
deaths causally related to treatment / all	0 / 6	0 / 4	0 / 8
HIV infection WHO clinical stage II			
subjects affected / exposed[258]	0 / 2976 (0.00%)	0 / 2972 (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[259]	0 / 2976 (0.00%)	0 / 2972 (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[260]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Impetigo			
subjects affected / exposed[261]	1 / 2976 (0.03%)	2 / 2972 (0.07%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed[262]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Infection			
subjects affected / exposed[263]	0 / 2976 (0.00%)	0 / 2972 (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[264]	0 / 2976 (0.00%)	0 / 2972 (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 cellulitis			
subjects affected / exposed[265]	1 / 2976 (0.03%)	0 / 2972 (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[266]	1 / 2976 (0.03%)	0 / 2972 (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 / 1	0 / 0	0 / 0
Laryngitis			

subjects affected / exposed[267]	1 / 2976 (0.03%)	0 / 2972 (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[268]	0 / 2976 (0.00%)	0 / 2972 (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[269]	0 / 2976 (0.00%)	0 / 2972 (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[270]	6 / 2976 (0.20%)	5 / 2972 (0.17%)	7 / 2974 (0.24%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Lower respiratory tract infection			
subjects affected / exposed[271]	2 / 2976 (0.07%)	3 / 2972 (0.10%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed[272]	2 / 2976 (0.07%)	0 / 2972 (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[273]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	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
Lymph node tuberculosis			
subjects affected / exposed[274]	1 / 2976 (0.03%)	0 / 2972 (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 / 1
Lymphadenitis bacterial			

subjects affected / exposed[275]	1 / 2976 (0.03%)	0 / 2972 (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[276]	294 / 2976 (9.88%)	342 / 2972 (11.51%)	421 / 2974 (14.16%)
occurrences causally related to treatment / all	0 / 294	0 / 342	0 / 421
deaths causally related to treatment / all	0 / 10	0 / 13	0 / 11
Mastoiditis			
subjects affected / exposed[277]	2 / 2976 (0.07%)	0 / 2972 (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[278]	7 / 2976 (0.24%)	2 / 2972 (0.07%)	5 / 2974 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Meningitis			
subjects affected / exposed[279]	5 / 2976 (0.17%)	5 / 2972 (0.17%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 1
Meningitis haemophilus			
subjects affected / exposed[280]	1 / 2976 (0.03%)	2 / 2972 (0.07%)	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 meningococcal			
subjects affected / exposed[281]	3 / 2976 (0.10%)	2 / 2972 (0.07%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed[282]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Meningitis salmonella			

subjects affected / exposed[283]	0 / 2976 (0.00%)	0 / 2972 (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[284]	1 / 2976 (0.03%)	0 / 2972 (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[285]	1 / 2976 (0.03%)	0 / 2972 (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[286]	0 / 2976 (0.00%)	0 / 2972 (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[287]	0 / 2976 (0.00%)	0 / 2972 (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[288]	0 / 2976 (0.00%)	0 / 2972 (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[289]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Oral candidiasis			
subjects affected / exposed[290]	5 / 2976 (0.17%)	5 / 2972 (0.17%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Oropharyngeal candidiasis			

subjects affected / exposed[291]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	0 / 2974 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed[292]	3 / 2976 (0.10%)	2 / 2972 (0.07%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed[293]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Otitis media			
subjects affected / exposed[294]	19 / 2976 (0.64%)	10 / 2972 (0.34%)	22 / 2974 (0.74%)
occurrences causally related to treatment / all	0 / 19	0 / 10	0 / 22
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Otitis media acute			
subjects affected / exposed[295]	2 / 2976 (0.07%)	2 / 2972 (0.07%)	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
Otitis media chronic			
subjects affected / exposed[296]	1 / 2976 (0.03%)	0 / 2972 (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[297]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal abscess			
subjects affected / exposed[298]	1 / 2976 (0.03%)	0 / 2972 (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[299]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Peritonitis			
subjects affected / exposed[300]	0 / 2976 (0.00%)	0 / 2972 (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[301]	1 / 2976 (0.03%)	0 / 2972 (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
Plasmodium ovale infection			
subjects affected / exposed[302]	0 / 2976 (0.00%)	0 / 2972 (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[303]	0 / 2976 (0.00%)	0 / 2972 (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[304]	5 / 2976 (0.17%)	4 / 2972 (0.13%)	3 / 2974 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed[305]	2 / 2976 (0.07%)	0 / 2972 (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 / 1	0 / 0	0 / 1
Pneumonia			
subjects affected / exposed[306]	202 / 2976 (6.79%)	215 / 2972 (7.23%)	223 / 2974 (7.50%)
occurrences causally related to treatment / all	0 / 202	0 / 215	0 / 223
deaths causally related to treatment / all	0 / 15	0 / 7	0 / 8
Pneumonia pneumococcal			

subjects affected / exposed[307]	0 / 2976 (0.00%)	0 / 2972 (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[308]	1 / 2976 (0.03%)	0 / 2972 (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[309]	0 / 2976 (0.00%)	0 / 2972 (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[310]	1 / 2976 (0.03%)	0 / 2972 (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[311]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Pulmonary tuberculosis			
subjects affected / exposed[312]	7 / 2976 (0.24%)	1 / 2972 (0.03%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed[313]	0 / 2976 (0.00%)	0 / 2972 (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[314]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Pyomyositis			

subjects affected / exposed[315]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Rabies			
subjects affected / exposed[316]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Respiratory tract infection			
subjects affected / exposed[317]	2 / 2976 (0.07%)	2 / 2972 (0.07%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Rubella			
subjects affected / exposed[318]	0 / 2976 (0.00%)	0 / 2972 (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[319]	0 / 2976 (0.00%)	0 / 2972 (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 sepsis			
subjects affected / exposed[320]	36 / 2976 (1.21%)	34 / 2972 (1.14%)	42 / 2974 (1.41%)
occurrences causally related to treatment / all	0 / 36	0 / 34	0 / 42
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Salmonellosis			
subjects affected / exposed[321]	1 / 2976 (0.03%)	3 / 2972 (0.10%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schistosomiasis			
subjects affected / exposed[322]	0 / 2976 (0.00%)	0 / 2972 (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[323]	33 / 2976 (1.11%)	27 / 2972 (0.91%)	43 / 2974 (1.45%)
occurrences causally related to treatment / all	0 / 33	0 / 27	0 / 43
deaths causally related to treatment / all	0 / 7	0 / 4	0 / 5
Septic shock			
subjects affected / exposed[324]	0 / 2976 (0.00%)	0 / 2972 (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[325]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Skin bacterial infection			
subjects affected / exposed[326]	2 / 2976 (0.07%)	0 / 2972 (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 / 1	0 / 0	0 / 0
Skin infection			
subjects affected / exposed[327]	3 / 2976 (0.10%)	0 / 2972 (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[328]	3 / 2976 (0.10%)	6 / 2972 (0.20%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed[329]	1 / 2976 (0.03%)	2 / 2972 (0.07%)	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
Streptococcal infection			
subjects affected / exposed[330]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Streptococcal sepsis			

subjects affected / exposed[331]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Subcutaneous abscess			
subjects affected / exposed[332]	5 / 2976 (0.17%)	4 / 2972 (0.13%)	2 / 2974 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			
subjects affected / exposed[333]	0 / 2976 (0.00%)	0 / 2972 (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[334]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Tinea capitis			
subjects affected / exposed[335]	0 / 2976 (0.00%)	0 / 2972 (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[336]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Toxic shock syndrome			
subjects affected / exposed[337]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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 / 1	0 / 0
Tracheobronchitis			
subjects affected / exposed[338]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Trichiniasis			

subjects affected / exposed[339]	0 / 2976 (0.00%)	0 / 2972 (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[340]	4 / 2976 (0.13%)	5 / 2972 (0.17%)	6 / 2974 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Typhoid fever			
subjects affected / exposed[341]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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 / 1
Upper respiratory tract infection			
subjects affected / exposed[342]	29 / 2976 (0.97%)	39 / 2972 (1.31%)	43 / 2974 (1.45%)
occurrences causally related to treatment / all	0 / 29	0 / 39	0 / 43
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urinary tract infection			
subjects affected / exposed[343]	22 / 2976 (0.74%)	23 / 2972 (0.77%)	28 / 2974 (0.94%)
occurrences causally related to treatment / all	0 / 22	0 / 23	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urinary tract infection bacterial			
subjects affected / exposed[344]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Urinary tract infection pseudomonal			
subjects affected / exposed[345]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Urosepsis			
subjects affected / exposed[346]	0 / 2976 (0.00%)	0 / 2972 (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[347]	0 / 2976 (0.00%)	0 / 2972 (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[348]	1 / 2976 (0.03%)	0 / 2972 (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
Viral infection			
subjects affected / exposed[349]	0 / 2976 (0.00%)	0 / 2972 (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[350]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Wound sepsis			
subjects affected / exposed[351]	0 / 2976 (0.00%)	0 / 2972 (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[352]	1 / 2976 (0.03%)	1 / 2972 (0.03%)	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
Failure to thrive			
subjects affected / exposed[353]	1 / 2976 (0.03%)	0 / 2972 (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
Hyperkalaemia			
subjects affected / exposed[354]	0 / 2976 (0.00%)	0 / 2972 (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[355]	10 / 2976 (0.34%)	10 / 2972 (0.34%)	18 / 2974 (0.61%)
occurrences causally related to treatment / all	0 / 10	0 / 10	0 / 18
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 1
Hypokalaemia			
subjects affected / exposed[356]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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
Hypoproteinaemia			
subjects affected / exposed[357]	0 / 2976 (0.00%)	2 / 2972 (0.07%)	1 / 2974 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kwashiorkor			
subjects affected / exposed[358]	11 / 2976 (0.37%)	4 / 2972 (0.13%)	17 / 2974 (0.57%)
occurrences causally related to treatment / all	0 / 11	0 / 4	0 / 17
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Malnutrition			
subjects affected / exposed[359]	27 / 2976 (0.91%)	27 / 2972 (0.91%)	21 / 2974 (0.71%)
occurrences causally related to treatment / all	0 / 27	0 / 27	0 / 21
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 3
Marasmus			
subjects affected / exposed[360]	6 / 2976 (0.20%)	8 / 2972 (0.27%)	4 / 2974 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 4	0 / 2
Metabolic acidosis			
subjects affected / exposed[361]	0 / 2976 (0.00%)	0 / 2972 (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[362]	0 / 2976 (0.00%)	1 / 2972 (0.03%)	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

Serious adverse events	R3R (6-12W) Group	R3C (6-12W) Group	RTS,S/AS01 (5-17M) Group

Total subjects affected by serious adverse events			
subjects affected / exposed	580 / 2180 (26.61%)	602 / 2178 (27.64%)	0 / 1479 (0.00%)
number of deaths (all causes)	51	55	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute promyelocytic leukaemia			
subjects affected / exposed[1]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed[2]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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[3]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Langerhans' cell histiocytosis			
subjects affected / exposed[4]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed[5]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed[6]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Shock			
subjects affected / exposed[7]	1 / 2180 (0.05%)	2 / 2178 (0.09%)	0 / 1 (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

General disorders and administration site conditions			
Death			
subjects affected / exposed[8]	2 / 2180 (0.09%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Drowning			
subjects affected / exposed[9]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed[10]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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[11]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed[12]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Injection site reaction			
subjects affected / exposed[13]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed[14]	15 / 2180 (0.69%)	11 / 2178 (0.51%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 15	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed[15]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anaphylactic reaction			
subjects affected / exposed[16]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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[17]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Social circumstances			
Child abuse			
subjects affected / exposed[18]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sexual abuse			
subjects affected / exposed[19]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed[20]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Apnoeic attack			
subjects affected / exposed[21]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			
subjects affected / exposed[22]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			

subjects affected / exposed[23]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed[24]	6 / 2180 (0.28%)	3 / 2178 (0.14%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed[25]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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[26]	3 / 2180 (0.14%)	5 / 2178 (0.23%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed[27]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed[28]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed[29]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed[30]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed[31]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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[32]	2 / 2180 (0.09%)	2 / 2178 (0.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pneumonitis			
subjects affected / exposed[33]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Pulmonary oedema			
subjects affected / exposed[34]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 acidosis			
subjects affected / exposed[35]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 arrest			
subjects affected / exposed[36]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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 disorder			
subjects affected / exposed[37]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Neurodevelopmental disorder			
subjects affected / exposed[38]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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[39]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental poisoning			
subjects affected / exposed[40]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed[41]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod sting			
subjects affected / exposed[42]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chemical			
subjects affected / exposed[43]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns first degree			
subjects affected / exposed[44]	2 / 2180 (0.09%)	0 / 2178 (0.00%)	0 / 1 (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
Burns second degree			
subjects affected / exposed[45]	3 / 2180 (0.14%)	2 / 2178 (0.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical injury			
subjects affected / exposed[46]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical poisoning			

subjects affected / exposed[47]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed[48]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Crush injury			
subjects affected / exposed[49]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disinfectant poisoning			
subjects affected / exposed[50]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exposure to toxic agent			
subjects affected / exposed[51]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye contusion			
subjects affected / exposed[52]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye injury			
subjects affected / exposed[53]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed[54]	2 / 2180 (0.09%)	2 / 2178 (0.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			

subjects affected / exposed[55]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body aspiration			
subjects affected / exposed[56]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured skull depressed			
subjects affected / exposed[57]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Greenstick fracture			
subjects affected / exposed[58]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed[59]	0 / 2180 (0.00%)	4 / 2178 (0.18%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Herbal toxicity			
subjects affected / exposed[60]	0 / 2180 (0.00%)	2 / 2178 (0.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Human bite			
subjects affected / exposed[61]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Humerus fracture			
subjects affected / exposed[62]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Joint injury			

subjects affected / exposed[63]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed[64]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed[65]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Limb traumatic amputation			
subjects affected / exposed[66]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penis injury			
subjects affected / exposed[67]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petroleum distillate poisoning			
subjects affected / exposed[68]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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 chemical			
subjects affected / exposed[69]	2 / 2180 (0.09%)	2 / 2178 (0.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning			
subjects affected / exposed[70]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary contusion			

subjects affected / exposed[71]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed[72]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatic nerve injury			
subjects affected / exposed[73]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin injury			
subjects affected / exposed[74]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Snake bite			
subjects affected / exposed[75]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed[76]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Thermal burn			
subjects affected / exposed[77]	14 / 2180 (0.64%)	9 / 2178 (0.41%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed[78]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaccination failure			

subjects affected / exposed[79]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Wound			
subjects affected / exposed[80]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed[81]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed[82]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 palsy			
subjects affected / exposed[83]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Choledochal cyst			
subjects affected / exposed[84]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital megacolon			
subjects affected / exposed[85]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cryptorchism			
subjects affected / exposed[86]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fallot’s tetralogy			

subjects affected / exposed[87]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed[88]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed[89]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed[90]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia			
subjects affected / exposed[91]	1 / 2180 (0.05%)	3 / 2178 (0.14%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sickle cell anaemia with crisis			
subjects affected / exposed[92]	1 / 2180 (0.05%)	4 / 2178 (0.18%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Trisomy 21			
subjects affected / exposed[93]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Urethral valves			
subjects affected / exposed[94]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Ventricular septal defect			

subjects affected / exposed[95]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 disorders			
Cardiac arrest			
subjects affected / exposed[96]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Cardiac failure			
subjects affected / exposed[97]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed[98]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed[99]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Arachnoid cyst			
subjects affected / exposed[100]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar ataxia			
subjects affected / exposed[101]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Cerebral atrophy			
subjects affected / exposed[102]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			

subjects affected / exposed[103]	45 / 2180 (2.06%)	32 / 2178 (1.47%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 45	0 / 32	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 4	0 / 0
Depressed level of consciousness			
subjects affected / exposed[104]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalomalacia			
subjects affected / exposed[105]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed[106]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Epilepsy			
subjects affected / exposed[107]	1 / 2180 (0.05%)	2 / 2178 (0.09%)	0 / 1 (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
Febrile convulsion			
subjects affected / exposed[108]	100 / 2180 (4.59%)	90 / 2178 (4.13%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	3 / 100	1 / 90	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 0
Haemorrhage intracranial			
subjects affected / exposed[109]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed[110]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			

subjects affected / exposed[111]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed[112]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Loss of consciousness			
subjects affected / exposed[113]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Meningism			
subjects affected / exposed[114]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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[115]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed[116]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Monoparesis			
subjects affected / exposed[117]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Myoclonus			
subjects affected / exposed[118]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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[119]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech disorder developmental			
subjects affected / exposed[120]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uraemic encephalopathy			
subjects affected / exposed[121]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed[122]	90 / 2180 (4.13%)	106 / 2178 (4.87%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 90	0 / 106	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 14	0 / 0
Dislocation of vertebra			
subjects affected / exposed[123]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed[124]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed[125]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed[126]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypochromic anaemia			

subjects affected / exposed[127]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intravascular haemolysis			
subjects affected / exposed[128]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemoid reaction			
subjects affected / exposed[129]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed[130]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Neutropenia			
subjects affected / exposed[131]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed[132]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed[133]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed[134]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Hearing impaired			

subjects affected / exposed[135]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Periorbital oedema			
subjects affected / exposed[136]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed[137]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed[138]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed[139]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Enteritis			
subjects affected / exposed[140]	7 / 2180 (0.32%)	10 / 2178 (0.46%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Food poisoning			
subjects affected / exposed[141]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed[142]	2 / 2180 (0.09%)	1 / 2178 (0.05%)	0 / 1 (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
Gastrointestinal haemorrhage			

subjects affected / exposed[143]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal motility disorder			
subjects affected / exposed[144]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed[145]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed[146]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed[147]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed[148]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Intestinal obstruction			
subjects affected / exposed[149]	2 / 2180 (0.09%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed[150]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			

subjects affected / exposed[151]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed[152]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
subjects affected / exposed[153]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed[154]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed[155]	2 / 2180 (0.09%)	0 / 2178 (0.00%)	0 / 1 (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
Stress ulcer			
subjects affected / exposed[156]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed[157]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia, obstructive			
subjects affected / exposed[158]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			

subjects affected / exposed[159]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed[160]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed[161]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Drug hypersensitivity			
subjects affected / exposed[162]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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			
subjects affected / exposed[163]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Hepatitis acute			
subjects affected / exposed[164]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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 toxic			
subjects affected / exposed[165]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune reconstitution inflammatory syndrome			
subjects affected / exposed[166]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Dermatitis			
subjects affected / exposed[167]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed[168]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative			
subjects affected / exposed[169]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Drug eruption			
subjects affected / exposed[170]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			
subjects affected / exposed[171]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed[172]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed[173]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed[174]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion			

subjects affected / exposed[175]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			
subjects affected / exposed[176]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed[177]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Vitiligo			
subjects affected / exposed[178]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Glomerulonephritis			
subjects affected / exposed[179]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis acute			
subjects affected / exposed[180]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed[181]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Nephritis			
subjects affected / exposed[182]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Nephrotic syndrome			

subjects affected / exposed[183]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 failure acute			
subjects affected / exposed[184]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Renal tubular necrosis			
subjects affected / exposed[185]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed[186]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed[187]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Compartment syndrome			
subjects affected / exposed[188]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Dactylitis			
subjects affected / exposed[189]	2 / 2180 (0.09%)	0 / 2178 (0.00%)	0 / 1 (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
Joint effusion			
subjects affected / exposed[190]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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[191]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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[192]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Rickets			
subjects affected / exposed[193]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Torticollis			
subjects affected / exposed[194]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed[195]	4 / 2180 (0.18%)	8 / 2178 (0.37%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			
subjects affected / exposed[196]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed[197]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed[198]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Acarodermatitis			

subjects affected / exposed[199]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AIDS dementia complex			
subjects affected / exposed[200]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed[201]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Arthritis bacterial			
subjects affected / exposed[202]	3 / 2180 (0.14%)	3 / 2178 (0.14%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascariasis			
subjects affected / exposed[203]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed[204]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed[205]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed[206]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone tuberculosis			

subjects affected / exposed[207]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed[208]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Breast abscess			
subjects affected / exposed[209]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed[210]	19 / 2180 (0.87%)	13 / 2178 (0.60%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 19	0 / 13	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed[211]	6 / 2180 (0.28%)	11 / 2178 (0.51%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed[212]	35 / 2180 (1.61%)	19 / 2178 (0.87%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 35	0 / 19	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 0
Bullous impetigo			
subjects affected / exposed[213]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Burkholderia cepacia complex sepsis			
subjects affected / exposed[214]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burn infection			

subjects affected / exposed[215]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Candida infection			
subjects affected / exposed[216]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Cellulitis			
subjects affected / exposed[217]	6 / 2180 (0.28%)	4 / 2178 (0.18%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis of male external genital organ			
subjects affected / exposed[218]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 orbital			
subjects affected / exposed[219]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 pharyngeal			
subjects affected / exposed[220]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system viral infection			
subjects affected / exposed[221]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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 malaria			
subjects affected / exposed[222]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cholera			

subjects affected / exposed[223]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed[224]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Conjunctivitis bacterial			
subjects affected / exposed[225]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Croup infectious			
subjects affected / exposed[226]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis infected			
subjects affected / exposed[227]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed[228]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			
subjects affected / exposed[229]	4 / 2180 (0.18%)	6 / 2178 (0.28%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Eczema infected			
subjects affected / exposed[230]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			

subjects affected / exposed[231]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed[232]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Encephalitis viral			
subjects affected / exposed[233]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Encephalomyelitis			
subjects affected / exposed[234]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			
subjects affected / exposed[235]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed[236]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed[237]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Escherichia urinary tract infection			
subjects affected / exposed[238]	1 / 2180 (0.05%)	2 / 2178 (0.09%)	0 / 1 (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
Exanthema subitum			

subjects affected / exposed[239]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed[240]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Furuncle			
subjects affected / exposed[241]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed[242]	162 / 2180 (7.43%)	171 / 2178 (7.85%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 162	0 / 171	0 / 0
deaths causally related to treatment / all	0 / 14	0 / 11	0 / 0
Gastroenteritis Escherichia coli			
subjects affected / exposed[243]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed[244]	5 / 2180 (0.23%)	2 / 2178 (0.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis shigella			
subjects affected / exposed[245]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed[246]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal candidiasis			

subjects affected / exposed[247]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giardiasis			
subjects affected / exposed[248]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Gingivitis			
subjects affected / exposed[249]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed[250]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Haemophilus sepsis			
subjects affected / exposed[251]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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[252]	1 / 2180 (0.05%)	2 / 2178 (0.09%)	0 / 1 (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
Hepatitis A			
subjects affected / exposed[253]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis B			
subjects affected / exposed[254]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis infectious			

subjects affected / exposed[255]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 associated nephropathy			
subjects affected / exposed[256]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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			
subjects affected / exposed[257]	20 / 2180 (0.92%)	16 / 2178 (0.73%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 16	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 5	0 / 0
HIV infection WHO clinical stage II			
subjects affected / exposed[258]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 III			
subjects affected / exposed[259]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
HIV infection WHO clinical stage IV			
subjects affected / exposed[260]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Impetigo			
subjects affected / exposed[261]	2 / 2180 (0.09%)	2 / 2178 (0.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed[262]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			

subjects affected / exposed[263]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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 abscess			
subjects affected / exposed[264]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 cellulitis			
subjects affected / exposed[265]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed[266]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed[267]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Listeria sepsis			
subjects affected / exposed[268]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Liver abscess			
subjects affected / exposed[269]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Lobar pneumonia			
subjects affected / exposed[270]	8 / 2180 (0.37%)	9 / 2178 (0.41%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed[271]	0 / 2180 (0.00%)	4 / 2178 (0.18%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed[272]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Lymph node abscess			
subjects affected / exposed[273]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Lymph node tuberculosis			
subjects affected / exposed[274]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis bacterial			
subjects affected / exposed[275]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed[276]	180 / 2180 (8.26%)	208 / 2178 (9.55%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 180	0 / 208	0 / 0
deaths causally related to treatment / all	0 / 6	0 / 9	0 / 0
Mastoiditis			
subjects affected / exposed[277]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Measles			
subjects affected / exposed[278]	14 / 2180 (0.64%)	10 / 2178 (0.46%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			

subjects affected / exposed[279]	2 / 2180 (0.09%)	3 / 2178 (0.14%)	0 / 1 (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
Meningitis haemophilus			
subjects affected / exposed[280]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Meningitis meningococcal			
subjects affected / exposed[281]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 pneumococcal			
subjects affected / exposed[282]	1 / 2180 (0.05%)	2 / 2178 (0.09%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Meningitis salmonella			
subjects affected / exposed[283]	2 / 2180 (0.09%)	1 / 2178 (0.05%)	0 / 1 (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
Meningitis tuberculous			
subjects affected / exposed[284]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 viral			
subjects affected / exposed[285]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Moraxella infection			
subjects affected / exposed[286]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Mumps			

subjects affected / exposed[287]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Mycobacterium ulcerans infection			
subjects affected / exposed[288]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed[289]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed[290]	1 / 2180 (0.05%)	2 / 2178 (0.09%)	0 / 1 (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
Oropharyngeal candidiasis			
subjects affected / exposed[291]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed[292]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Otitis externa			
subjects affected / exposed[293]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Otitis media			
subjects affected / exposed[294]	11 / 2180 (0.50%)	11 / 2178 (0.51%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Otitis media acute			

subjects affected / exposed[295]	2 / 2180 (0.09%)	1 / 2178 (0.05%)	0 / 1 (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
Otitis media chronic			
subjects affected / exposed[296]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed[297]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Perineal abscess			
subjects affected / exposed[298]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed[299]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed[300]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Pharyngitis			
subjects affected / exposed[301]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmodium ovale infection			
subjects affected / exposed[302]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 bacteraemia			

subjects affected / exposed[303]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Pneumococcal sepsis			
subjects affected / exposed[304]	5 / 2180 (0.23%)	4 / 2178 (0.18%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed[305]	4 / 2180 (0.18%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Pneumonia			
subjects affected / exposed[306]	217 / 2180 (9.95%)	206 / 2178 (9.46%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 217	0 / 206	0 / 0
deaths causally related to treatment / all	0 / 12	0 / 15	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed[307]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Pneumonia streptococcal			
subjects affected / exposed[308]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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[309]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Postoperative wound infection			
subjects affected / exposed[310]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			

subjects affected / exposed[311]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed[312]	6 / 2180 (0.28%)	6 / 2178 (0.28%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyelonephritis			
subjects affected / exposed[313]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma			
subjects affected / exposed[314]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyomyositis			
subjects affected / exposed[315]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (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
Rabies			
subjects affected / exposed[316]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 tract infection			
subjects affected / exposed[317]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Rubella			
subjects affected / exposed[318]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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 bacteraemia			

subjects affected / exposed[319]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 sepsis			
subjects affected / exposed[320]	25 / 2180 (1.15%)	34 / 2178 (1.56%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 25	0 / 34	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Salmonellosis			
subjects affected / exposed[321]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schistosomiasis			
subjects affected / exposed[322]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed[323]	23 / 2180 (1.06%)	15 / 2178 (0.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 23	0 / 15	0 / 0
deaths causally related to treatment / all	0 / 6	0 / 5	0 / 0
Septic shock			
subjects affected / exposed[324]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Shigella infection			
subjects affected / exposed[325]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed[326]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed[327]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed[328]	5 / 2180 (0.23%)	5 / 2178 (0.23%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed[329]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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 infection			
subjects affected / exposed[330]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed[331]	1 / 2180 (0.05%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Subcutaneous abscess			
subjects affected / exposed[332]	6 / 2180 (0.28%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			
subjects affected / exposed[333]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Taeniasis			
subjects affected / exposed[334]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea capitis			

subjects affected / exposed[335]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed[336]	1 / 2180 (0.05%)	2 / 2178 (0.09%)	0 / 1 (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
Toxic shock syndrome			
subjects affected / exposed[337]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed[338]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trichiniasis			
subjects affected / exposed[339]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed[340]	2 / 2180 (0.09%)	4 / 2178 (0.18%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Typhoid fever			
subjects affected / exposed[341]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed[342]	19 / 2180 (0.87%)	31 / 2178 (1.42%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 19	0 / 31	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed[343]	11 / 2180 (0.50%)	15 / 2178 (0.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 15	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed[344]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed[345]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed[346]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal infection			
subjects affected / exposed[347]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Varicella			
subjects affected / exposed[348]	2 / 2180 (0.09%)	1 / 2178 (0.05%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Viral infection			
subjects affected / exposed[349]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed[350]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
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 sepsis			

subjects affected / exposed[351]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed[352]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Failure to thrive			
subjects affected / exposed[353]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Hyperkalaemia			
subjects affected / exposed[354]	0 / 2180 (0.00%)	1 / 2178 (0.05%)	0 / 1 (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
Hypoglycaemia			
subjects affected / exposed[355]	2 / 2180 (0.09%)	3 / 2178 (0.14%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypokalaemia			
subjects affected / exposed[356]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoproteinaemia			
subjects affected / exposed[357]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kwashiorkor			
subjects affected / exposed[358]	8 / 2180 (0.37%)	8 / 2178 (0.37%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Malnutrition			

subjects affected / exposed[359]	20 / 2180 (0.92%)	30 / 2178 (1.38%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 30	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 0
Marasmus			
subjects affected / exposed[360]	6 / 2180 (0.28%)	5 / 2178 (0.23%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Metabolic acidosis			
subjects affected / exposed[361]	1 / 2180 (0.05%)	0 / 2178 (0.00%)	0 / 1 (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
Underweight			
subjects affected / exposed[362]	0 / 2180 (0.00%)	0 / 2178 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	C3C (6-12W) Group	RTS,S/AS01 (6-12W) Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	619 / 2179 (28.41%)	0 / 1462 (0.00%)	
number of deaths (all causes)	42	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute promyelocytic leukaemia			
subjects affected / exposed[1]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed[2]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory pseudotumour			

subjects affected / exposed[3]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Langerhans' cell histiocytosis			
subjects affected / exposed[4]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haematoma			
subjects affected / exposed[5]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed[6]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed[7]	4 / 2179 (0.18%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed[8]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Drowning			
subjects affected / exposed[9]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Generalised oedema			
subjects affected / exposed[10]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hernia			
subjects affected / exposed[11]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed[12]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site reaction			
subjects affected / exposed[13]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed[14]	18 / 2179 (0.83%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	2 / 18	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed[15]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed[16]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed[17]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Child abuse			
subjects affected / exposed[18]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Sexual abuse			
subjects affected / exposed[19]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed[20]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Apnoeic attack			
subjects affected / exposed[21]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
subjects affected / exposed[22]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed[23]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed[24]	7 / 2179 (0.32%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial hyperreactivity			
subjects affected / exposed[25]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			

subjects affected / exposed[26]	5 / 2179 (0.23%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed[27]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed[28]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed[29]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed[30]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed[31]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed[32]	4 / 2179 (0.18%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed[33]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			

subjects affected / exposed[34]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory acidosis			
subjects affected / exposed[35]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed[36]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory disorder			
subjects affected / exposed[37]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Neurodevelopmental disorder			
subjects affected / exposed[38]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed[39]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental poisoning			
subjects affected / exposed[40]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed[41]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Arthropod sting			
subjects affected / exposed[42]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis chemical			
subjects affected / exposed[43]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns first degree			
subjects affected / exposed[44]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns second degree			
subjects affected / exposed[45]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical injury			
subjects affected / exposed[46]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical poisoning			
subjects affected / exposed[47]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed[48]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crush injury			
subjects affected / exposed[49]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disinfectant poisoning			

subjects affected / exposed[50]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exposure to toxic agent			
subjects affected / exposed[51]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye contusion			
subjects affected / exposed[52]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye injury			
subjects affected / exposed[53]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed[54]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body			
subjects affected / exposed[55]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body aspiration			
subjects affected / exposed[56]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured skull depressed			
subjects affected / exposed[57]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Greenstick fracture			

subjects affected / exposed[58]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed[59]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herbal toxicity			
subjects affected / exposed[60]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Human bite			
subjects affected / exposed[61]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed[62]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed[63]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed[64]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed[65]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb traumatic amputation			

subjects affected / exposed[66]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penis injury			
subjects affected / exposed[67]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Petroleum distillate poisoning			
subjects affected / exposed[68]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis chemical			
subjects affected / exposed[69]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning			
subjects affected / exposed[70]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary contusion			
subjects affected / exposed[71]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed[72]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatic nerve injury			
subjects affected / exposed[73]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin injury			

subjects affected / exposed[74]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Snake bite			
subjects affected / exposed[75]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue injury			
subjects affected / exposed[76]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed[77]	11 / 2179 (0.50%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 11	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tibia fracture			
subjects affected / exposed[78]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaccination failure			
subjects affected / exposed[79]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed[80]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed[81]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			

subjects affected / exposed[82]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral palsy			
subjects affected / exposed[83]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choledochal cyst			
subjects affected / exposed[84]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital megacolon			
subjects affected / exposed[85]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryptorchism			
subjects affected / exposed[86]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fallot’s tetralogy			
subjects affected / exposed[87]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed[88]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed[89]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			

subjects affected / exposed[90]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sickle cell anaemia			
subjects affected / exposed[91]	5 / 2179 (0.23%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sickle cell anaemia with crisis			
subjects affected / exposed[92]	5 / 2179 (0.23%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trisomy 21			
subjects affected / exposed[93]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral valves			
subjects affected / exposed[94]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect			
subjects affected / exposed[95]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed[96]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed[97]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			

subjects affected / exposed[98]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed[99]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Arachnoid cyst			
subjects affected / exposed[100]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar ataxia			
subjects affected / exposed[101]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral atrophy			
subjects affected / exposed[102]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed[103]	32 / 2179 (1.47%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 32	0 / 0	
deaths causally related to treatment / all	0 / 4	0 / 0	
Depressed level of consciousness			
subjects affected / exposed[104]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalomalacia			
subjects affected / exposed[105]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			

subjects affected / exposed[106]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed[107]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile convulsion			
subjects affected / exposed[108]	101 / 2179 (4.64%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 101	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed[109]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed[110]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			
subjects affected / exposed[111]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed[112]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed[113]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningism			

subjects affected / exposed[114]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental retardation			
subjects affected / exposed[115]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed[116]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoparesis			
subjects affected / exposed[117]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonus			
subjects affected / exposed[118]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed[119]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Speech disorder developmental			
subjects affected / exposed[120]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uraemic encephalopathy			
subjects affected / exposed[121]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed[122]	116 / 2179 (5.32%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 116	0 / 0	
deaths causally related to treatment / all	0 / 4	0 / 0	
Dislocation of vertebra			
subjects affected / exposed[123]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed[124]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolysis			
subjects affected / exposed[125]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic anaemia			
subjects affected / exposed[126]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypochromic anaemia			
subjects affected / exposed[127]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intravascular haemolysis			
subjects affected / exposed[128]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemoid reaction			
subjects affected / exposed[129]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			

subjects affected / exposed[130]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed[131]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed[132]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed[133]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed[134]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hearing impaired			
subjects affected / exposed[135]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Periorbital oedema			
subjects affected / exposed[136]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed[137]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Colitis			
subjects affected / exposed[138]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed[139]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed[140]	18 / 2179 (0.83%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 18	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Food poisoning			
subjects affected / exposed[141]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed[142]	4 / 2179 (0.18%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed[143]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal motility disorder			
subjects affected / exposed[144]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed[145]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			

subjects affected / exposed[146]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed[147]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed[148]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed[149]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed[150]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed[151]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth ulceration			
subjects affected / exposed[152]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed[153]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse			

subjects affected / exposed[154]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed[155]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress ulcer			
subjects affected / exposed[156]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed[157]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia, obstructive			
subjects affected / exposed[158]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed[159]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed[160]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed[161]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			

subjects affected / exposed[162]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed[163]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed[164]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis toxic			
subjects affected / exposed[165]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune reconstitution inflammatory syndrome			
subjects affected / exposed[166]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed[167]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed[168]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis exfoliative			
subjects affected / exposed[169]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug eruption			

subjects affected / exposed[170]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema multiforme			
subjects affected / exposed[171]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed[172]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash maculo-papular			
subjects affected / exposed[173]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash papular			
subjects affected / exposed[174]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin lesion			
subjects affected / exposed[175]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stevens-Johnson syndrome			
subjects affected / exposed[176]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed[177]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitiligo			

subjects affected / exposed[178]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Glomerulonephritis			
subjects affected / exposed[179]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis acute			
subjects affected / exposed[180]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed[181]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephritis			
subjects affected / exposed[182]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed[183]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure acute			
subjects affected / exposed[184]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed[185]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			

subjects affected / exposed[186]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed[187]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed[188]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dactylitis			
subjects affected / exposed[189]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed[190]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed[191]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed[192]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rickets			
subjects affected / exposed[193]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torticollis			

subjects affected / exposed[194]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess			
subjects affected / exposed[195]	5 / 2179 (0.23%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess jaw			
subjects affected / exposed[196]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed[197]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed[198]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acarodermatitis			
subjects affected / exposed[199]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
AIDS dementia complex			
subjects affected / exposed[200]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amoebiasis			
subjects affected / exposed[201]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			

subjects affected / exposed[202]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascariasis			
subjects affected / exposed[203]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
subjects affected / exposed[204]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed[205]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed[206]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone tuberculosis			
subjects affected / exposed[207]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain abscess			
subjects affected / exposed[208]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast abscess			
subjects affected / exposed[209]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			

subjects affected / exposed[210]	24 / 2179 (1.10%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 24	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed[211]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchopneumonia			
subjects affected / exposed[212]	34 / 2179 (1.56%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 34	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Bullous impetigo			
subjects affected / exposed[213]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burkholderia cepacia complex sepsis			
subjects affected / exposed[214]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burn infection			
subjects affected / exposed[215]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida infection			
subjects affected / exposed[216]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed[217]	6 / 2179 (0.28%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis of male external genital organ			

subjects affected / exposed[218]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis orbital			
subjects affected / exposed[219]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis pharyngeal			
subjects affected / exposed[220]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system viral infection			
subjects affected / exposed[221]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral malaria			
subjects affected / exposed[222]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholera			
subjects affected / exposed[223]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			
subjects affected / exposed[224]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis bacterial			
subjects affected / exposed[225]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Croup infectious			

subjects affected / exposed[226]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis infected			
subjects affected / exposed[227]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated tuberculosis			
subjects affected / exposed[228]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysentery			
subjects affected / exposed[229]	7 / 2179 (0.32%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema infected			
subjects affected / exposed[230]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed[231]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed[232]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Encephalitis viral			
subjects affected / exposed[233]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalomyelitis			

subjects affected / exposed[234]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal sepsis			
subjects affected / exposed[235]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed[236]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed[237]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed[238]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exanthema subitum			
subjects affected / exposed[239]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile infection			
subjects affected / exposed[240]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed[241]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			

subjects affected / exposed[242]	171 / 2179 (7.85%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 171	0 / 0	
deaths causally related to treatment / all	0 / 10	0 / 0	
Gastroenteritis Escherichia coli			
subjects affected / exposed[243]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed[244]	4 / 2179 (0.18%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis shigella			
subjects affected / exposed[245]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed[246]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal candidiasis			
subjects affected / exposed[247]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giardiasis			
subjects affected / exposed[248]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingivitis			
subjects affected / exposed[249]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			

subjects affected / exposed[250]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus sepsis			
subjects affected / exposed[251]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helminthic infection			
subjects affected / exposed[252]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			
subjects affected / exposed[253]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B			
subjects affected / exposed[254]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis infectious			
subjects affected / exposed[255]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV associated nephropathy			
subjects affected / exposed[256]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
HIV infection			
subjects affected / exposed[257]	12 / 2179 (0.55%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 12	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
HIV infection WHO clinical stage II			

subjects affected / exposed[258]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV infection WHO clinical stage III			
subjects affected / exposed[259]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV infection WHO clinical stage IV			
subjects affected / exposed[260]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impetigo			
subjects affected / exposed[261]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed[262]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed[263]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site abscess			
subjects affected / exposed[264]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site cellulitis			
subjects affected / exposed[265]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			

subjects affected / exposed[266]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed[267]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Listeria sepsis			
subjects affected / exposed[268]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed[269]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobar pneumonia			
subjects affected / exposed[270]	7 / 2179 (0.32%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed[271]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ludwig angina			
subjects affected / exposed[272]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymph node abscess			
subjects affected / exposed[273]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymph node tuberculosis			

subjects affected / exposed[274]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis bacterial			
subjects affected / exposed[275]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaria			
subjects affected / exposed[276]	233 / 2179 (10.69%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 233	0 / 0	
deaths causally related to treatment / all	0 / 4	0 / 0	
Mastoiditis			
subjects affected / exposed[277]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Measles			
subjects affected / exposed[278]	8 / 2179 (0.37%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 8	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed[279]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningitis haemophilus			
subjects affected / exposed[280]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis meningococcal			
subjects affected / exposed[281]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis pneumococcal			

subjects affected / exposed[282]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Meningitis salmonella			
subjects affected / exposed[283]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis tuberculous			
subjects affected / exposed[284]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis viral			
subjects affected / exposed[285]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Moraxella infection			
subjects affected / exposed[286]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mumps			
subjects affected / exposed[287]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterium ulcerans infection			
subjects affected / exposed[288]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed[289]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			

subjects affected / exposed[290]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal candidiasis			
subjects affected / exposed[291]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed[292]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed[293]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed[294]	7 / 2179 (0.32%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed[295]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed[296]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed[297]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			

subjects affected / exposed[298]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed[299]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed[300]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed[301]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmodium ovale infection			
subjects affected / exposed[302]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal bacteraemia			
subjects affected / exposed[303]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed[304]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed[305]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed[306]	202 / 2179 (9.27%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 202	0 / 0	
deaths causally related to treatment / all	0 / 9	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed[307]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia streptococcal			
subjects affected / exposed[308]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed[309]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed[310]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal sepsis			
subjects affected / exposed[311]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed[312]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed[313]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyoderma			

subjects affected / exposed[314]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyomyositis			
subjects affected / exposed[315]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rabies			
subjects affected / exposed[316]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed[317]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rubella			
subjects affected / exposed[318]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonella bacteraemia			
subjects affected / exposed[319]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonella sepsis			
subjects affected / exposed[320]	37 / 2179 (1.70%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 37	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Salmonellosis			
subjects affected / exposed[321]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schistosomiasis			

subjects affected / exposed[322]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed[323]	13 / 2179 (0.60%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 13	0 / 0	
deaths causally related to treatment / all	0 / 5	0 / 0	
Septic shock			
subjects affected / exposed[324]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shigella infection			
subjects affected / exposed[325]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin bacterial infection			
subjects affected / exposed[326]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed[327]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed[328]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal skin infection			
subjects affected / exposed[329]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal infection			

subjects affected / exposed[330]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed[331]	2 / 2179 (0.09%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Subcutaneous abscess			
subjects affected / exposed[332]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superinfection			
subjects affected / exposed[333]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Taeniasis			
subjects affected / exposed[334]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinea capitis			
subjects affected / exposed[335]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed[336]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic shock syndrome			
subjects affected / exposed[337]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			

subjects affected / exposed[338]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trichiniasis			
subjects affected / exposed[339]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed[340]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Typhoid fever			
subjects affected / exposed[341]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed[342]	24 / 2179 (1.10%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 24	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed[343]	22 / 2179 (1.01%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 22	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed[344]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection pseudomonal			
subjects affected / exposed[345]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed[346]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal infection			
subjects affected / exposed[347]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed[348]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed[349]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed[350]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed[351]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed[352]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed[353]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			

subjects affected / exposed[354]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed[355]	3 / 2179 (0.14%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypokalaemia			
subjects affected / exposed[356]	1 / 2179 (0.05%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoproteinaemia			
subjects affected / exposed[357]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kwashiorkor			
subjects affected / exposed[358]	4 / 2179 (0.18%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed[359]	19 / 2179 (0.87%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 19	0 / 0	
deaths causally related to treatment / all	0 / 5	0 / 0	
Marasmus			
subjects affected / exposed[360]	7 / 2179 (0.32%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Metabolic acidosis			
subjects affected / exposed[361]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Underweight			

subjects affected / exposed[362]	0 / 2179 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns

coded as '0'.

[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
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[20] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
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[122] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[123] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[124] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[125] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[126] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[127] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[128] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[129] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[131] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[132] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[134] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[135] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[136] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[139] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[143] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[144] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[145] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[146] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[147] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[156] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[159] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[160] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[161] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[164] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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[165] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[341] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[342] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[343] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[344] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[345] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[346] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[347] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[348] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[349] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

[350] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[351] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[352] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[353] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[354] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[355] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[356] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[357] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[358] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[359] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[360] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[361] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.
[362] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In this section, RTS,S/AS01 (5-17M) & RTS,S/AS01 (6-12W) groups are only applicable for solicited & unsolicited AEs post PRI vaccination, with all not applicable other Ns coded as '1' and ns coded as '0'.

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

Non-serious adverse events	R3R (5-17M) Group	R3C (5-17M) Group	C3C (5-17M) Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	233 / 2976 (7.83%)	205 / 2972 (6.90%)	626 / 2974 (21.05%)
General disorders and administration site conditions			
Pain – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[363]	0 / 1 (0.00%)	0 / 1 (0.00%)	105 / 721 (14.56%)
occurrences (all)	0	0	105
Redness – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[364]	0 / 1 (0.00%)	0 / 1 (0.00%)	49 / 721 (6.80%)
occurrences (all)	0	0	49
Swelling – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[365]	0 / 1 (0.00%)	0 / 1 (0.00%)	119 / 721 (16.50%)
occurrences (all)	0	0	119
Pain – BST			
alternative assessment type: Systematic			
subjects affected / exposed[366]	109 / 641 (17.00%)	45 / 639 (7.04%)	41 / 633 (6.48%)
occurrences (all)	109	45	41
Swelling – BST			
alternative assessment type: Systematic			
subjects affected / exposed[367]	42 / 641 (6.55%)	35 / 639 (5.48%)	30 / 633 (4.74%)
occurrences (all)	42	35	30
Drowsiness - PRI			
alternative assessment type: Systematic			
subjects affected / exposed[368]	0 / 1 (0.00%)	0 / 1 (0.00%)	78 / 721 (10.82%)
occurrences (all)	0	0	78
Irritability – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[369]	0 / 1 (0.00%)	0 / 1 (0.00%)	96 / 721 (13.31%)
occurrences (all)	0	0	96
Loss of appetite - PRI			
alternative assessment type: Systematic			

subjects affected / exposed[370]	0 / 1 (0.00%)	0 / 1 (0.00%)	132 / 721 (18.31%)
occurrences (all)	0	0	132
Fever (axillary temperature ≥37.5° C) - PRI			
alternative assessment type: Systematic			
subjects affected / exposed[371]	0 / 1 (0.00%)	0 / 1 (0.00%)	235 / 721 (32.59%)
occurrences (all)	0	0	235
Drowsiness – BST			
alternative assessment type: Systematic			
subjects affected / exposed[372]	55 / 641 (8.58%)	22 / 639 (3.44%)	21 / 633 (3.32%)
occurrences (all)	55	22	21
Irritability – BST			
alternative assessment type: Systematic			
subjects affected / exposed[373]	63 / 641 (9.83%)	25 / 639 (3.91%)	18 / 633 (2.84%)
occurrences (all)	63	25	18
Loss of appetite – BST			
alternative assessment type: Systematic			
subjects affected / exposed[374]	66 / 641 (10.30%)	27 / 639 (4.23%)	21 / 633 (3.32%)
occurrences (all)	66	27	21
Fever (axillary temperature ≥37.5° C) - BST			
alternative assessment type: Systematic			
subjects affected / exposed[375]	233 / 641 (36.35%)	70 / 639 (10.95%)	45 / 633 (7.11%)
occurrences (all)	233	70	45
Pyrexia – PRI			
subjects affected / exposed[376]	0 / 1 (0.00%)	0 / 1 (0.00%)	67 / 721 (9.29%)
occurrences (all)	0	0	67
Pyrexia - BST			
subjects affected / exposed[377]	44 / 641 (6.86%)	10 / 639 (1.56%)	7 / 633 (1.11%)
occurrences (all)	44	10	7
Gastrointestinal disorders			
Diarrhoea - PRI			
subjects affected / exposed[378]	0 / 1 (0.00%)	0 / 1 (0.00%)	88 / 721 (12.21%)
occurrences (all)	0	0	88
Respiratory, thoracic and mediastinal disorders			

Cough - PRI			
subjects affected / exposed[379]	0 / 1 (0.00%)	0 / 1 (0.00%)	41 / 721 (5.69%)
occurrences (all)	0	0	41
Infections and infestations			
Conjunctivitis – PRI			
subjects affected / exposed[380]	0 / 1 (0.00%)	0 / 1 (0.00%)	64 / 721 (8.88%)
occurrences (all)	0	0	64
Enteritis – PRI			
subjects affected / exposed[381]	0 / 1 (0.00%)	0 / 1 (0.00%)	62 / 721 (8.60%)
occurrences (all)	0	0	62
Gastroenteritis- PRI			
subjects affected / exposed[382]	0 / 1 (0.00%)	0 / 1 (0.00%)	170 / 721 (23.58%)
occurrences (all)	0	0	170
Malaria- PRI			
subjects affected / exposed[383]	0 / 1 (0.00%)	0 / 1 (0.00%)	173 / 721 (23.99%)
occurrences (all)	0	0	173
Nasopharyngitis – PRI			
subjects affected / exposed[384]	0 / 1 (0.00%)	0 / 1 (0.00%)	58 / 721 (8.04%)
occurrences (all)	0	0	58
Pneumonia – PRI			
subjects affected / exposed[385]	0 / 1 (0.00%)	0 / 1 (0.00%)	71 / 721 (9.85%)
occurrences (all)	0	0	71
Rhinitis – PRI			
subjects affected / exposed[386]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 721 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection – PRI			
subjects affected / exposed[387]	0 / 1 (0.00%)	0 / 1 (0.00%)	326 / 721 (45.21%)
occurrences (all)	0	0	326
Malaria - BST			
subjects affected / exposed[388]	49 / 641 (7.64%)	53 / 639 (8.29%)	84 / 633 (13.27%)
occurrences (all)	49	53	84
Upper respiratory tract infection – BST			
subjects affected / exposed[389]	61 / 641 (9.52%)	55 / 639 (8.61%)	55 / 633 (8.69%)
occurrences (all)	61	55	55
Gastroenteritis - BST			

subjects affected / exposed[390]	17 / 641 (2.65%)	16 / 639 (2.50%)	13 / 633 (2.05%)
occurrences (all)	17	16	13

Non-serious adverse events	R3R (6-12W) Group	R3C (6-12W) Group	RTS,S/AS01 (5-17M) Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	231 / 2180 (10.60%)	239 / 2178 (10.97%)	1273 / 1479 (86.07%)
General disorders and administration site conditions			
Pain – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[363]	0 / 1 (0.00%)	0 / 1 (0.00%)	401 / 1479 (27.11%)
occurrences (all)	0	0	401
Redness – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[364]	0 / 1 (0.00%)	0 / 1 (0.00%)	122 / 1479 (8.25%)
occurrences (all)	0	0	122
Swelling – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[365]	0 / 1 (0.00%)	0 / 1 (0.00%)	303 / 1479 (20.49%)
occurrences (all)	0	0	303
Pain – BST			
alternative assessment type: Systematic			
subjects affected / exposed[366]	59 / 608 (9.70%)	29 / 625 (4.64%)	0 / 1 (0.00%)
occurrences (all)	59	29	0
Swelling – BST			
alternative assessment type: Systematic			
subjects affected / exposed[367]	45 / 608 (7.40%)	28 / 625 (4.48%)	0 / 1 (0.00%)
occurrences (all)	45	28	0
Drowsiness - PRI			
alternative assessment type: Systematic			
subjects affected / exposed[368]	0 / 1 (0.00%)	0 / 1 (0.00%)	230 / 1479 (15.55%)
occurrences (all)	0	0	230
Irritability – PRI			
alternative assessment type: Systematic			

subjects affected / exposed[369]	0 / 1 (0.00%)	0 / 1 (0.00%)	369 / 1479 (24.95%)
occurrences (all)	0	0	369
Loss of appetite - PRI			
alternative assessment type: Systematic			
subjects affected / exposed[370]	0 / 1 (0.00%)	0 / 1 (0.00%)	398 / 1479 (26.91%)
occurrences (all)	0	0	398
Fever (axillary temperature ≥37.5° C) - PRI			
alternative assessment type: Systematic			
subjects affected / exposed[371]	0 / 1 (0.00%)	0 / 1 (0.00%)	897 / 1479 (60.65%)
occurrences (all)	0	0	897
Drowsiness – BST			
alternative assessment type: Systematic			
subjects affected / exposed[372]	33 / 608 (5.43%)	19 / 625 (3.04%)	0 / 1 (0.00%)
occurrences (all)	33	19	0
Irritability – BST			
alternative assessment type: Systematic			
subjects affected / exposed[373]	46 / 608 (7.57%)	23 / 625 (3.68%)	0 / 1 (0.00%)
occurrences (all)	46	23	0
Loss of appetite – BST			
alternative assessment type: Systematic			
subjects affected / exposed[374]	45 / 608 (7.40%)	27 / 625 (4.32%)	0 / 1 (0.00%)
occurrences (all)	45	27	0
Fever (axillary temperature ≥37.5° C) - BST			
alternative assessment type: Systematic			
subjects affected / exposed[375]	152 / 608 (25.00%)	52 / 625 (8.32%)	0 / 1 (0.00%)
occurrences (all)	152	52	0
Pyrexia – PRI			
subjects affected / exposed[376]	0 / 1 (0.00%)	0 / 1 (0.00%)	200 / 1479 (13.52%)
occurrences (all)	0	0	200
Pyrexia - BST			
subjects affected / exposed[377]	12 / 608 (1.97%)	11 / 625 (1.76%)	0 / 1 (0.00%)
occurrences (all)	12	11	0
Gastrointestinal disorders			

Diarrhoea - PRI			
subjects affected / exposed[378]	0 / 1 (0.00%)	0 / 1 (0.00%)	188 / 1479 (12.71%)
occurrences (all)	0	0	188
Respiratory, thoracic and mediastinal disorders			
Cough - PRI			
subjects affected / exposed[379]	0 / 1 (0.00%)	0 / 1 (0.00%)	107 / 1479 (7.23%)
occurrences (all)	0	0	107
Infections and infestations			
Conjunctivitis – PRI			
subjects affected / exposed[380]	0 / 1 (0.00%)	0 / 1 (0.00%)	111 / 1479 (7.51%)
occurrences (all)	0	0	111
Enteritis – PRI			
subjects affected / exposed[381]	0 / 1 (0.00%)	0 / 1 (0.00%)	124 / 1479 (8.38%)
occurrences (all)	0	0	124
Gastroenteritis- PRI			
subjects affected / exposed[382]	0 / 1 (0.00%)	0 / 1 (0.00%)	372 / 1479 (25.15%)
occurrences (all)	0	0	372
Malaria- PRI			
subjects affected / exposed[383]	0 / 1 (0.00%)	0 / 1 (0.00%)	265 / 1479 (17.92%)
occurrences (all)	0	0	265
Nasopharyngitis – PRI			
subjects affected / exposed[384]	0 / 1 (0.00%)	0 / 1 (0.00%)	115 / 1479 (7.78%)
occurrences (all)	0	0	115
Pneumonia – PRI			
subjects affected / exposed[385]	0 / 1 (0.00%)	0 / 1 (0.00%)	166 / 1479 (11.22%)
occurrences (all)	0	0	166
Rhinitis – PRI			
subjects affected / exposed[386]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1479 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection – PRI			
subjects affected / exposed[387]	0 / 1 (0.00%)	0 / 1 (0.00%)	638 / 1479 (43.14%)
occurrences (all)	0	0	638
Malaria - BST			

subjects affected / exposed[388]	34 / 608 (5.59%)	29 / 625 (4.64%)	0 / 1 (0.00%)
occurrences (all)	34	29	0
Upper respiratory tract infection – BST			
subjects affected / exposed[389]	44 / 608 (7.24%)	56 / 625 (8.96%)	0 / 1 (0.00%)
occurrences (all)	44	56	0
Gastroenteritis - BST			
subjects affected / exposed[390]	231 / 608 (37.99%)	239 / 625 (38.24%)	0 / 1 (0.00%)
occurrences (all)	231	239	0

Non-serious adverse events	C3C (6-12W) Group	RTS,S/AS01 (6-12W) Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	600 / 2179 (27.54%)	1161 / 1462 (79.41%)	
General disorders and administration site conditions			
Pain – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[363]	342 / 738 (46.34%)	705 / 1462 (48.22%)	
occurrences (all)	342	705	
Redness – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[364]	163 / 738 (22.09%)	292 / 1462 (19.97%)	
occurrences (all)	163	292	
Swelling – PRI			
alternative assessment type: Systematic			
subjects affected / exposed[365]	248 / 738 (33.60%)	427 / 1462 (29.21%)	
occurrences (all)	248	427	
Pain – BST			
alternative assessment type: Systematic			
subjects affected / exposed[366]	25 / 621 (4.03%)	0 / 1 (0.00%)	
occurrences (all)	25	0	
Swelling – BST			
alternative assessment type: Systematic			
subjects affected / exposed[367]	43 / 621 (6.92%)	0 / 1 (0.00%)	
occurrences (all)	43	0	

Drowsiness - PRI				
alternative assessment type: Systematic				
subjects affected / exposed[368]	121 / 738 (16.40%)	285 / 1462 (19.49%)		
occurrences (all)	121	285		
Irritability – PRI				
alternative assessment type: Systematic				
subjects affected / exposed[369]	244 / 738 (33.06%)	574 / 1462 (39.26%)		
occurrences (all)	244	574		
Loss of appetite - PRI				
alternative assessment type: Systematic				
subjects affected / exposed[370]	104 / 738 (14.09%)	243 / 1462 (16.62%)		
occurrences (all)	104	243		
Fever (axillary temperature ≥37.5° C) - PRI				
alternative assessment type: Systematic				
subjects affected / exposed[371]	331 / 738 (44.85%)	839 / 1462 (57.39%)		
occurrences (all)	331	839		
Drowsiness – BST				
alternative assessment type: Systematic				
subjects affected / exposed[372]	15 / 621 (2.42%)	0 / 1 (0.00%)		
occurrences (all)	15	0		
Irritability – BST				
alternative assessment type: Systematic				
subjects affected / exposed[373]	23 / 621 (3.70%)	0 / 1 (0.00%)		
occurrences (all)	23	0		
Loss of appetite – BST				
alternative assessment type: Systematic				
subjects affected / exposed[374]	18 / 621 (2.90%)	0 / 1 (0.00%)		
occurrences (all)	18	0		
Fever (axillary temperature ≥37.5° C) - BST				
alternative assessment type: Systematic				
subjects affected / exposed[375]	58 / 621 (9.34%)	0 / 1 (0.00%)		
occurrences (all)	58	0		
Pyrexia – PRI				

subjects affected / exposed[376]	112 / 738 (15.18%)	251 / 1462 (17.17%)	
occurrences (all)	112	251	
Pyrexia - BST			
subjects affected / exposed[377]	39 / 621 (6.28%)	0 / 1 (0.00%)	
occurrences (all)	39	0	
Gastrointestinal disorders			
Diarrhoea - PRI			
subjects affected / exposed[378]	0 / 738 (0.00%)	0 / 1462 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough - PRI			
subjects affected / exposed[379]	0 / 738 (0.00%)	0 / 1462 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Conjunctivitis – PRI			
subjects affected / exposed[380]	63 / 738 (8.54%)	118 / 1462 (8.07%)	
occurrences (all)	63	118	
Enteritis – PRI			
subjects affected / exposed[381]	72 / 738 (9.76%)	131 / 1462 (8.96%)	
occurrences (all)	72	131	
Gastroenteritis- PRI			
subjects affected / exposed[382]	131 / 738 (17.75%)	220 / 1462 (15.05%)	
occurrences (all)	131	220	
Malaria- PRI			
subjects affected / exposed[383]	70 / 738 (9.49%)	137 / 1462 (9.37%)	
occurrences (all)	70	137	
Nasopharyngitis – PRI			
subjects affected / exposed[384]	55 / 738 (7.45%)	76 / 1462 (5.20%)	
occurrences (all)	55	76	
Pneumonia – PRI			
subjects affected / exposed[385]	39 / 738 (5.28%)	86 / 1462 (5.88%)	
occurrences (all)	39	86	
Rhinitis – PRI			
subjects affected / exposed[386]	75 / 738 (10.16%)	148 / 1462 (10.12%)	
occurrences (all)	75	148	

Upper respiratory tract infection – PRI			
subjects affected / exposed[387]	312 / 738 (42.28%)	584 / 1462 (39.95%)	
occurrences (all)	312	584	
Malaria - BST			
subjects affected / exposed[388]	40 / 621 (6.44%)	0 / 1 (0.00%)	
occurrences (all)	40	0	
Upper respiratory tract infection – BST			
subjects affected / exposed[389]	55 / 621 (8.86%)	0 / 1 (0.00%)	
occurrences (all)	55	0	
Gastroenteritis - BST			
subjects affected / exposed[390]	240 / 621 (38.65%)	0 / 1 (0.00%)	
occurrences (all)	240	0	

Notes:

[363] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[364] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[365] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[366] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[367] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[368] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[369] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[370] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[371] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[372] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.

[373] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[374] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[375] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[376] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[377] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[378] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[379] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[380] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[381] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[382] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[383] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[384] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[385] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[386] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[387] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[388] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as '1' and ns coded as '0'.
[389] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are

only applicable for solicited SAEs, with all not applicable other Ns coded as ‘1’ and ns coded as ‘0’.

[390] - 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: In this section, R3R (5-17M), R3C (5-17M), R3R (6-12W) and R3C (6-12W) groups are only applicable for solicited SAEs, with all not applicable other Ns coded as ‘1’ and ns coded as ‘0’.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 August 2008	The primary objective and endpoint were updated to make them case-driven. The number of episodes needed to have sufficient power and precision to evaluate the primary endpoint was added to the protocol. In the original protocol, malaria episodes occurring within 28 days of a previous episode were excluded from the analysis, to avoid including recrudescence of the first infection. However, since writing the protocol, all sites switched to highly effective first line therapy with artemisin combinations and recrudescence were rare. Therefore, the period of exclusion was reduced to 14 days to reflect the half-lives of these new therapeutic regimens and consequently the shorter period of time for which individuals were non-susceptible after anti-malarial therapy.
24 October 2008	RTS protein is derived from a sporozoite surface antigen of the Plasmodium falciparum strain NF54. Previous studies showed that protection was not limited to the NF54 parasite genotype. As part of Amendment 2, the collection of study samples for the determination of parasite genotyping to evaluate strain-specific efficacy and protection against infection due to multiple strains was added.
26 November 2009	Based on a theoretical concern that the use of new adjuvanted vaccines could promote a rupture of immunological self-tolerance, regulatory authorities required optimizing the data collection on immune-mediated diseases (IMD). As a result, GSK Biologicals decided to define IMD as adverse events of interest and to optimize auto-immunity data collection processes in studies of all GSK's adjuvanted candidate vaccines. The protocol was adapted accordingly. The assessment of all unsolicited adverse events (AEs) in the first 200 subjects enrolled in each age category and at each study site was added in Amendment 3. The assessment of serious adverse events (SAEs) occurring within 30 days of each vaccination dose was added to the protocol in order to better assess any temporal relationship between SAE occurrence and variation across all studies performed at GSK Biologicals. The exclusion criterion on anemia was clarified by splitting the information over two lines. Anemia was defined as hemoglobin < 5.0 g/dL or or hemoglobin < 8 g/dL associated with clinical signs of heart failure or severe respiratory distress.
01 December 2010	This amendment 4 was done to increase the follow up period of the study. All subjects having their Visit 34 before and including on 30 September 2013 will be followed up. Due to the wide range of enrolment, there will be a variable number of months of follow-up after vaccination for individual children. Based on the actual enrolment, the mean follow-up time will be 49 months post Dose 1 (range: 41-55) for the 5 to 17 months age category and 41 months post Dose 1 (range: 32-48) for the 6 to 12 weeks age category. The protocol was amended to collect data on severe malaria; malaria hospitalization and parasite prevalence in the 11 participating centers using the same methodologies and case definitions as in the primary trial phase. Occurrence of SAEs will be monitored in all 11 centers. Surveillance for clinical malaria will take place in at least 3 centers with varying transmission levels. Immunogenicity endpoints will also be collected on a subset of individuals from both age categories in at least these 3 centers.

23 January 2012	Amendment 5 was developed to include an analysis time point at Month 20 (18 months post Dose 3). No changes have been made to the protocol endpoints or statistical methods but the protocol endpoints will be analyzed on data collected up to Month 20 as soon as these data are available. The rationale is to have the full scope of protocol defined efficacy and safety endpoints related to a primary schedule without booster in both age categories followed up for 20 months earlier than at study end (Visit 34) as initially planned. The detailed analysis of gender-specific vaccine efficacy will be reported in full at the end of the study (Visit 34). Also, the text related to the recording of concomitant medication was adapted to allow more flexibility in the collection of data on concomitant medication during the study.
08 August 2012	Amendment 6 was developed related to that, at a request from the European Medicines Agency's (EMA), GSK Biologicals has updated its procedure for emergency unblinding during the conduct of a clinical study. According to the revised procedure, the responsibility and the decision to break the treatment code in emergency situations resides solely with the investigator and consequently, the investigator will have full authority to break the treatment code. Investigators will be granted an unrestricted, immediate and direct access to the individual treatment codes via an automated system.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported