Clinical trial results:
A Phase II randomized, open, controlled study of the safety and immunogenicity of GlaxoSmithKline Biologicals' candidate Plasmodium falciparum malaria vaccine RTS,S/AS01E, when incorporated into an Expanded Program on Immunization (EPI) regimen that includes DTPwHepB/Hib, OPV, measles and yellow fever vaccination in infants living in malaria-endemic regions.

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2012-005695-34
Trial protocol	Outside EU/EEA
Global end of trial date	07 October 2009

Results information

Result version number	v2
This version publication date	08 July 2016
First version publication date	18 July 2015
Version creation reason	• Correction of full data set Data correction due to a system error in EudraCT – Results

Trial information

Trial identification

Sponsor protocol code	106369

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00436007
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 208990 4466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 208990 4466, 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	09 July 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 October 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety (SAEs) of RTS,S/AS01E when co-administered on a 0, 1, 2-month schedule with DTPwHepB/Hib and OPV at 6, 10 and 14 weeks of age, until 6 months post Dose 3 of RTS,S/AS01E (study Month 8), and when co-administered on a 0, 1, 7-month schedule with DTPwHepB/Hib and OPV at 6 and 10 weeks of age then with measles and yellow fever vaccination at 9 months of age, until one month post Dose 3 of RTS,S/AS01E (study Month 8).

Protection of trial subjects:

All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines. Subjects were followed-up for safety events from the time the subject consents to participate in the study until she/he is discharged. Subjects were also followed-up as regards infection with malaria, by passive case detection (PCD). Parents were advised to present their child to a health facility within the study area when he/she was unwell. When a subject was presented to a health facility within a study area, he/she was reviewed by clinically qualified personnel and treated as required. The temperature was recorded and if 37.5C, a blood slide was performed to test for malari infection. A rapid test was performed to guide immediate patient management, when assessed as needed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 2007
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	11 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Tanzania, United Republic of: 210
Country: Number of subjects enrolled	Ghana: 81
Country: Number of subjects enrolled	Gabon: 220
Worldwide total number of subjects	511
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)	511
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 comprised a vaccination phase (Months 0-8) and a follow-up phase (Months 8-19). The Stamaril™ vaccine was not part of the EPI Tanzanian vaccination schedule at study planning. Hence this vaccine was not administered to subjects from Tanzania.

Pre-assignment

Screening details:

The study comprised a vaccination phase (Months 0-8) and a follow-up phase (Months 8-19). The Stamaril™ vaccine was not part of the EPI Tanzanian vaccination schedule at study planning. Hence this vaccine was not administered to subjects from Tanzania.

Pre-assignment period milestones

Number of subjects started	511
Number of subjects completed	511

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK 257049 1 Group

Arm description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), Polio Sabin™ and GSK 257049 vaccines at Months 0, 1 and 2, and a single dose of Rouvax™ and Stamaril™ vaccines at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. The Stamaril™ vaccine was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

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

Dosage and administration details:

Intramuscular administration in the left antero-lateral thigh at specified timepoints (see group description details).

Investigational medicinal product name	Rouvax
Investigational medicinal product code	
Other name	AMV, Rouvax™
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use, Subcutaneous use

Dosage and administration details:

Intramuscular administration in the left arm at specified timepoints (see group description details).

Investigational medicinal product name	Stamaril
Investigational medicinal product code	
Other name	Yellow Fever Vaccine (YFV), Stamaril™
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration in the right arm at specified timepoints (see group description details).

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

Dosage and administration details:

Oral administration at specified time points (see group description details)

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

Dosage and administration details:

Intramuscular administration in the right antero-lateral thigh at specified time points (see group description details)

Investigational medicinal product name	Hiberix
Investigational medicinal product code	
Other name	Hib, HiberixTM
Pharmaceutical forms	Powder and solvent for solution for injection/skin-prick test
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration in the right antero-lateral thigh at specified time points (see group description details)

Arm title	GSK 257049 2 Group

Arm description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), and Polio Sabin™ at Months 0, 1 and 2, 3 doses of GSK 257049 vaccine at Months 0, 1 and 7, and a single dose of Rouvax™ and Stamaril™ at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. Stamaril™ was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

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

Dosage and administration details:

Intramuscular administration in the left antero-lateral thigh at specified timepoints (see group description details).

Investigational medicinal product name	Rouvax
Investigational medicinal product code	
Other name	AMV, Rouvax™
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use, Subcutaneous use

Dosage and administration details:

Intramuscular administration in the left arm at specified timepoints (see group description details).

Investigational medicinal product name	Stamaril
Investigational medicinal product code	
Other name	Yellow Fever Vaccine (YFV), Stamaril™
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration in the right arm at specified timepoints (see group description details).

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

Dosage and administration details:

Oral administration at specified time points (see group description details)

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

Dosage and administration details:

Intramuscular administration in the right antero-lateral thigh at specified time points (see group description details)

Investigational medicinal product name	Hiberix
Investigational medicinal product code	
Other name	Hib, HiberixTM
Pharmaceutical forms	Powder and solvent for solution for injection/skin-prick test
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration in the right antero-lateral thigh at specified time points (see group description details)

Arm title	Tritanrix™ HepB/Hiberix™ Group

Arm description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), and Polio Sabin™ at Months 0, 1 and 2, and a single dose of Rouvax™ and Stamaril™ at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. The Stamaril™ vaccine was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

Arm type	Active comparator
Investigational medicinal product name	Rouvax
Investigational medicinal product code	
Other name	AMV, Rouvax™
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use, Subcutaneous use

Dosage and administration details:

Intramuscular administration in the left arm at specified timepoints (see group description details).

Investigational medicinal product name	Stamaril
Investigational medicinal product code	
Other name	Yellow Fever Vaccine (YFV), Stamaril™
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details: Intramuscular administration in the right arm at specified timepoints (see group description details).	
Investigational medicinal product name	Polio Sabin (Oral)
Investigational medicinal product code	
Other name	Polio Sabin™, Oral Polio vaccine (OPV)
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use
Dosage and administration details: Oral administration at specified time points (see group description details)	
Investigational medicinal product name	DTPw-HBV
Investigational medicinal product code	
Other name	Tritanrix HepB,TritanrixTM-HepB
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular administration in the right antero-lateral thigh at specified time points (see group description details)	
Investigational medicinal product name	Hiberix
Investigational medicinal product code	
Other name	Hib, HiberixTM
Pharmaceutical forms	Powder and solvent for solution for injection/skin-prick test
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular administration in the right antero-lateral thigh at specified time points (see group description details)	

Number of subjects in period 1	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group
Started	170	170	171
Completed	151	156	148
Not completed	19	14	23
Consent withdrawn by subject	5	3	4
Physician decision	-	-	2
Death	-	1	3
Unspecified	-	-	1
Lost to follow-up	14	10	13

Baseline characteristics

Reporting groups	
Reporting group title	GSK 257049 1 Group
Reporting group description:	
Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), Polio Sabin™ and GSK 257049 vaccines at Months 0, 1 and 2, and a single dose of Rouvax™ and Stamaril™ vaccines at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. The Stamaril™ vaccine was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.	
Reporting group title	GSK 257049 2 Group
Reporting group description:	
Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), and Polio Sabin™ at Months 0, 1 and 2, 3 doses of GSK 257049 vaccine at Months 0, 1 and 7, and a single dose of Rouvax™ and Stamaril™ at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. Stamaril™ was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.	
Reporting group title	Tritanrix™ HepB/Hiberix™ Group
Reporting group description:	
Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), and Polio Sabin™ at Months 0, 1 and 2, and a single dose of Rouvax™ and Stamaril™ at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. The Stamaril™ vaccine was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.	

Reporting group values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group
Number of subjects	170	170	171
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	170	170	171
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: weeks			
arithmetic mean	7	7.1	7
standard deviation	± 0.97	± 1.05	± 0.97

Gender categorical Units: Subjects			
Female	90	84	78
Male	80	86	93

Reporting group values	Total		
Number of subjects	511		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	511		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous Units: weeks			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	252		
Male	259		

End points

End points reporting groups

Reporting group title	GSK 257049 1 Group

Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), Polio Sabin™ and GSK 257049 vaccines at Months 0, 1 and 2, and a single dose of Rouvax™ and Stamaril™ vaccines at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. The Stamaril™ vaccine was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

Reporting group title	GSK 257049 2 Group

Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), and Polio Sabin™ at Months 0, 1 and 2, 3 doses of GSK 257049 vaccine at Months 0, 1 and 7, and a single dose of Rouvax™ and Stamaril™ at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. Stamaril™ was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

Reporting group title	Tritanrix™ HepB/Hiberix™ Group

Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), and Polio Sabin™ at Months 0, 1 and 2, and a single dose of Rouvax™ and Stamaril™ at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. The Stamaril™ vaccine was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

Primary: Number of subjects with serious adverse events (SAEs).

End point title	Number of subjects with serious adverse events (SAEs).[1]

End point description:

SAEs were defined as medical occurrences that resulted in death, were life threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity.

End point type	Primary

End point timeframe:

From Month 0 to Month 8

Notes:

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

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	170	171	
Units: Subjects				
Subjects with any SAE(s)	38	28	33	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events (SAEs).

End point title	Number of subjects with serious adverse events (SAEs).[2]

End point description:

SAEs were defined as medical occurrences that resulted in death, were life threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity.

End point type	Primary

End point timeframe:

From Month 8 to Month 19

Notes:

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

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	170	171	
Units: Subjects				
Subjects with any SAE(s)	28	24	27	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of antibodies against hepatitis B (Anti-HB antibodies).

End point title	Concentrations of antibodies against hepatitis B (Anti-HB antibodies).[3]

End point description:

Anti-HB antibody concentrations were expressed as geometric mean concentrations (GMCs) in milli-international unit per milliliter (mIU/mL). The seroprotection assay cut-off was 10 mIU/mL. This outcome only covers results for the GSK 257049 1 Group.

End point type	Secondary

End point timeframe:

At Months 0, 1, 3 and 7

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis and results presented solely concern the groups as per specified by endpoint description.

End point values	GSK 257049 1 Group			
Subject group type	Reporting group			
Number of subjects analysed	145			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HB, Month 0 [N=145]	12.5 (9.9 to 15.7)			
Anti-HB, Month 1 [N=133]	173.4 (131.9 to 228)			
Anti-HB, Month 3 [N=130]	1355.7 (1100.6 to 1669.9)			
Anti-HB, Month 7 [N=137]	1555.5 (1315.8 to 1839)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of antibodies against hepatitis B (Anti-HB antibodies).

End point title	Concentrations of antibodies against hepatitis B (Anti-HB antibodies).[4]

End point description:

Anti-HB antibody concentrations were expressed as geometric mean concentrations (GMCs) in milli-international unit per milliliter (mIU/mL). The seroprotection assay cut-off was 10 mIU/mL. This outcome only covers results for the GSK 257049 2 Group.

End point type	Secondary

End point timeframe:

At Months 0, 3, 7 and 8

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: Analysis and results presented solely concern the groups as per specified by endpoint description.

End point values	GSK 257049 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	131			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HB, Month 0 [N=131]	9.6 (7.8 to 11.8)			
Anti-HB, Month 3 [N=119]	651.2 (541.1 to 783.8)			
Anti-HB, Month 7 [N=126]	1133.1 (972.3 to 1320.6)			
Anti-HB, Month 8 [N=125]	59813.5 (47050.5 to 76038.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of antibodies against hepatitis B (Anti-HB antibodies).

End point title	Concentrations of antibodies against hepatitis B (Anti-HB antibodies).[5]

End point description:

Anti-HB antibody concentrations were expressed as geometric mean concentrations (GMCs) in milli-international unit per milliliter (mIU/mL). The seroprotection assay cut-off was 10 mIU/mL. This outcome only covers results for the Tritanrix™ HepB/Hiberix™ Group.

End point type	Secondary

End point timeframe:

At Months 0, 3, 7 and 8

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis and results presented solely concern the groups as per specified by endpoint description.

End point values	Tritanrix™ HepB/Hiberix™ Group			
Subject group type	Reporting group			
Number of subjects analysed	143			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HB, Month 0 [N=143]	8.7 (7.3 to 10.5)			
Anti-HB, Month 3 [N=126]	338 (266.3 to 429)			
Anti-HB, Month 7 [N=131]	159.9 (127 to 201.3)			
Anti-HB, Month 8 [N=133]	162.4 (127.9 to 206.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-diphtheria (Anti-D) and anti-tetanus (Anti-T) antibodies.

End point title	Concentrations of anti-diphtheria (Anti-D) and anti-tetanus (Anti-T) antibodies.

End point description:

Anti-D and Anti-T antibody concentrations were expressed as geometric mean concentrations (GMCs) in

international unit per milliliter (IU/mL). The seroprotection assay cut-off was 0.1 IU/mL.

End point type	Secondary

End point timeframe:

At Month 3

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	142	133	142	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D	1 (0.9 to 1.2)	1.1 (0.9 to 1.3)	1.4 (1.2 to 1.7)	
Anti-T	2.8 (2.3 to 3.3)	2.6 (2.2 to 3.1)	3.7 (3.2 to 4.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-polyribosyl ribitol phosphate (Anti-PRP) antibodies.

End point title	Concentrations of anti-polyribosyl ribitol phosphate (Anti-PRP) antibodies.

End point description:

Anti-PRP antibody concentrations were expressed as geometric mean concentrations (GMCs) in microgram per milliliter (µg/mL). The seroprotection assay cut-off was 0.15 µg/mL.

End point type	Secondary

End point timeframe:

At Month 3

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	141	132	142	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP	13.3 (10.5 to 16.7)	15.7 (12.6 to 19.4)	18.6 (14.8 to 23.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for antibodies against poliomyelitis types 1, 2 and 3 (Anti-Polio 1, 2 and 3 antibodies).

End point title	Titers for antibodies against poliomyelitis types 1, 2 and 3 (Anti-Polio 1, 2 and 3 antibodies).

End point description:

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

End point type	Secondary

End point timeframe:

At Month 3

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	136	125	133	
Units: titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1 [N=136;125;131]	463.6 (342.8 to 627)	485.5 (342.5 to 688.3)	500 (365 to 684.9)	
Anti-Polio 2 [N=135;124;131]	494 (389.7 to 626.2)	563.2 (457.3 to 693.6)	406.8 (329.1 to 502.9)	
Anti-Polio 3 [N=135;125;133]	123.5 (92.1 to 165.6)	148.7 (112.2 to 197)	205.1 (156.5 to 268.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-Bordetella pertussis toxin (Anti-BPT) antibodies.

End point title	Concentrations of anti-Bordetella pertussis toxin (Anti-BPT) antibodies.

End point description:

Anti-BPT antibodies were measured by enzyme-linked immunosorbent assay (ELISA). Concentrations were expressed as geometric mean concentrations (GMCs) in ELISA unit per milliliter (EL.U/mL). The seropositivity assay cut-off was 15 EL.U/mL.

End point type	Secondary

End point timeframe:

At Month 3

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	139	131	139	
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT	85.3 (76.8 to 94.6)	104.4 (94.8 to 115)	106.5 (96.1 to 118.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-measles antibodies.

End point title	Concentrations of anti-measles antibodies.[6]

End point description:

Anti-measles antibody concentrations were expressed as geometric mean concentrations (GMCs) in milli-international unit per milliliter (mIU/mL). The seropositivity assay cut-off was 150 mIU/mL. The analysis was only performed on subjects from the GSK 257049 2 and Tritanrix™ HepB/Hiberix™ groups.

End point type	Secondary

End point timeframe:

At Months 7 and 8

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis and results presented solely concern the groups as per specified by endpoint description.

End point values	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	122		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-measles, Month 7 [N=112;120]	75 (75 to 75)	76.2 (73.8 to 78.6)		
Anti-measles, Month 8 [N=119;122]	1295.2 (1052.1 to 1594.5)	1299 (1038.8 to 1624.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for anti-yellow fever antibodies.

End point title	Titers for anti-yellow fever antibodies.[7]

End point description:

Anti-yellow fever antibody titers were expressed as geometric mean titers (GMTs). The seroprotection assay cut-off was 10. The analysis was only performed on subjects from the GSK 257049 2 and Tritanrix™ HepB/Hiberix™ groups. The analysis was only performed on subjects from the GSK 257049 2 and Tritanrix™ HepB/Hiberix™ groups.

End point type	Secondary

End point timeframe:

At Months 7 and 8.

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: Analysis and results presented solely concern the groups as per specified by endpoint description.

End point values	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	64		
Units: titers				
geometric mean (confidence interval 95%)				
Anti-yellow fever, Month 7 [N=41;46]	5.3 (4.8 to 5.8)	5.9 (5.1 to 6.9)		
Anti-yellow fever, Month 8 [N=62;64]	179.2 (135.9 to 236.3)	183.4 (134 to 250.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-circumsporozoite protein (Anti-CS) antibodies.

End point title	Concentrations of anti-circumsporozoite protein (Anti-CS) antibodies.[8]

End point description:

Anti-CS antibody antibodies were measured by enzyme-linked immunosorbent assay (ELISA). Concentrations were expressed as geometric mean concentrations (GMCs) in ELISA unit per milliliter (EL.U/mL). The seropositivity assay cut-off was 0.5 EL.U/mL. This outcome only covers results for the GSK 257049 1 Group.

End point type	Secondary

End point timeframe:

At Months 0, 1, 3 and 7

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: Analysis and results presented solely concern the groups as per specified by endpoint description.

End point values	GSK 257049 1 Group			
Subject group type	Reporting group			
Number of subjects analysed	153			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Month 0 [N=153]	0.4 (0.3 to 0.4)			

Anti-CS, Month 2 [N=137]	86.6 (66.5 to 112.7)			
Anti-CS, Month 3 [N=131]	190.3 (154.3 to 234.7)			
Anti-CS, Month 7 [N=137]	35.3 (28.5 to 43.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-circumsporozoite protein (Anti-CS) antibodies.

End point title	Concentrations of anti-circumsporozoite protein (Anti-CS) antibodies.[9]

End point description:

Anti-CS antiibodies were measured by enzyme-linked immunosorbent assay (ELISA). Concentrations were expressed as geometric mean concentrations (GMCs) in ELISA unit per milliliter (EL.U/mL). The seropositivity assay cut-off was 0.5 EL.U/mL. This outcome only covers results for the GSK 257049 2 Group.

End point type	Secondary

End point timeframe:

At Months 0, 3, 7 and 8

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: Analysis and results presented solely concern the groups as per specified by endpoint description.

End point values	GSK 257049 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	141			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Month 0 [N=141]	0.4 (0.3 to 0.4)			
Anti-CS, Month 3 [N=121]	57.7 (43.7 to 76.2)			
Anti-CS, Month 7 [N=127]	6.1 (4.6 to 7.9)			
Anti-CS, Month 8 [N=127]	107.8 (81.1 to 143.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-circumsporozoite protein (Anti-CS) antibodies.

End point title	Concentrations of anti-circumsporozoite protein (Anti-CS) antibodies.[10]

End point description:

Anti-CS antibodies were measured by Enzyme-linked immunosorbent assay (ELISA). Concentrations were expressed as geometric mean concentrations (GMCs) in ELISA unit per milliliter (EL.U/mL). The

seropositivity assay cut-off was 0.5 EL.U/mL. This outcome only covers results for the Tritanrix™ HepB/Hiberix™ Group.

End point type	Secondary

End point timeframe:

At Months 0, 3, 7 and 8

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: Analysis and results presented solely concern the groups as per specified by endpoint description.

End point values	Tritanrix™ HepB/Hiberix™ Group			
Subject group type	Reporting group			
Number of subjects analysed	156			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Month 0 [N=156]	0.4 (0.3 to 0.4)			
Anti-CS, Month 3 [N=129]	0.3 (0.3 to 0.3)			
Anti-CS, Month 7 [N=132]	0.3 (0.3 to 0.3)			
Anti-CS, Month 8 [N=135]	0.3 (0.3 to 0.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms.

End point title	Number of subjects with solicited local symptoms.

End point description:

Assessed solicited local symptoms were pain and swelling at injection site following vaccination with each of the following study vaccines administered intramuscularly, e. a. the Tritanrix™ HepB/Hib, Rouvax™, GSK 257049 and Stamaril™ vaccines. The numbers of subjects with each of the assessed solicited local symptoms reported were tabulated for each vaccine administered, separately.

End point type	Secondary

End point timeframe:

During the 7-day (Days 0-6) follow-up period after any vaccination with the Tritanrix™ HepB/Hib, Rouvax™, GSK 257049 and Stamaril™ vaccines

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	170	171	
Units: Subjects				
Pain - GSK 257049 [N=170;170;0]	126	116	0	
Swelling - GSK 257049 [N=170;170;0]	28	44	0	
Pain - Rouvax™ [N=163;161;159]	52	54	47	

Swelling - Rouvax™ [N=163;161;159]	20	21	16	
Pain - Stamaril™ [N=95;94;94]	2	7	2	
Swelling - Stamaril™ [N=95;94;94]	0	1	0	
Pain - Tritanrix™ HepB/Hib [N=170;170;171]	127	133	140	
Swelling - Tritanrix™ HepB/Hib [N=170;170;171]	47	68	68	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.

End point description:

Assessed solicited general symptoms were drowsiness, fever [axillary temperature equal or above (≥) 37.5 degrees Celsius (°C)], irritability and loss of appetite following any vaccination with any of the study vaccines, e. a. the Tritanrix™ HepB/Hib, Rouvax™, GSK 257049, Stamaril™ and Polio Sabin™ vaccines.

End point type	Secondary

End point timeframe:

During the 7-day (Days 0-6) follow-up period after any vaccination

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	170	171	
Units: Subjects				
Drowsiness	82	97	72	
Fever (axillary temperature ≥ 37.5°C)	102	95	75	
Irritability	124	131	118	
Loss of appetite	68	83	70	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An unsolicited AE is any AE (i.e. any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with use of a medicinal product, whether or not considered related to the medicinal product) reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Unsolicited AEs were assessed following vaccination with any of the study vaccines, e. a. the Tritanrix™ HepB/Hib, Rouvax™, GSK 257049, Stamaril™ and Polio Sabin™ vaccines.

End point type	Secondary

End point timeframe:

During the 30-day (Days 0-29) follow-up period after any vaccination

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	170	171	
Units: Subjects				
Subjects with any AE(s)	160	161	164	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs).

End point title	Number of subjects with serious adverse events (SAEs).

End point description:

SAEs were defined as medical occurrences that resulted in death, were life threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity.

End point type	Secondary

End point timeframe:

From Month 0 to Month 19

End point values	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	170	171	
Units: Subjects				
Subjects with any SAE(s)	57	47	49	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

SAEs: Months [M] 0-19, as specified for each event; Solicited local (per specified vaccine)/general & Unsolicited AEs: 7- and 30-day post-vaccination periods, respectively. "1" was entered as n at risk if a group is not concerned by a specified event.

Adverse event reporting additional description:

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

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13.0

Reporting groups

Reporting group title	GSK 257049 1 Group

Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), Polio Sabin™ and GSK 257049 vaccines at Months 0, 1 and 2, and a single dose of Rouvax™ and Stamaril™ vaccines at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. The Stamaril™ vaccine was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

Reporting group title	GSK 257049 2 Group

Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), and Polio Sabin™ at Months 0, 1 and 2, 3 doses of GSK 257049 vaccine at Months 0, 1 and 7, and a single dose of Rouvax™ and Stamaril™ at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. Stamaril™ was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

Reporting group title	Tritanrix™ HepB/Hiberix™ Group

Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix™ HepB/Hib (reconstituted from Tritanrix™ HepB and Hiberix™), and Polio Sabin™ at Months 0, 1 and 2, 3 doses of GSK 257049 vaccine at Months 0, 1 and 7, and a single dose of Rouvax™ and Stamaril™ at Month 7. The GSK 257049 and Tritanrix™ HepB/Hib vaccines were administered intramuscularly in the left and right antero-lateral thigh, respectively. Rouvax™ and Stamaril™ were administered intramuscularly in the left and right arm respectively. Polio Sabin™ was administered orally. Stamaril™ was not administered to subjects from Tanzania as this vaccine was not foreseen at the time to be introduced to the EPI vaccination schedule in Tanzania.

Serious adverse events	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group
Total subjects affected by serious adverse events			
subjects affected / exposed	57 / 170 (33.53%)	47 / 170 (27.65%)	49 / 171 (28.65%)
number of deaths (all causes)	0	1	4
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
General disorders and administration site conditions			
Pyrexia (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (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
Bronchial hyperreactivity (M0 to8)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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
Pneumonia aspiration (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (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
Asthma (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	2 / 170 (1.18%)	0 / 171 (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
Injury, poisoning and procedural complications			
Thermal burn (M8 to 19)			

subjects affected / exposed	2 / 170 (1.18%)	0 / 170 (0.00%)	0 / 171 (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
Accidental exposure (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petroleum distillate poisoning (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis chemical (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Sickle cell anaemia (M0-8)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (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
Cataract congenital (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (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

Nervous system disorders			
Febrile convulsion (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	4 / 170 (2.35%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	2 / 170 (1.18%)	0 / 171 (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
Blood and lymphatic system disorders			
Anaemia (M0 to 8)			
subjects affected / exposed	6 / 170 (3.53%)	10 / 170 (5.88%)	10 / 171 (5.85%)
occurrences causally related to treatment / all	0 / 6	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Microcytic anaemia (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (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
Anaemia (M8 to 19)			
subjects affected / exposed	6 / 170 (3.53%)	6 / 170 (3.53%)	10 / 171 (5.85%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemolytic anaemia (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (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			
Blepharitis (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (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
Conjunctivitis (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
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 (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis (M0 to 8)			
subjects affected / exposed	17 / 170 (10.00%)	10 / 170 (5.88%)	14 / 171 (8.19%)
occurrences causally related to treatment / all	0 / 17	0 / 10	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmodium falciparum infection (M0-8)			

subjects affected / exposed	5 / 170 (2.94%)	10 / 170 (5.88%)	13 / 171 (7.60%)
occurrences causally related to treatment / all	0 / 5	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia (M0 to 8)			
subjects affected / exposed	11 / 170 (6.47%)	9 / 170 (5.29%)	8 / 171 (4.68%)
occurrences causally related to treatment / all	0 / 11	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Upper respiratory tract infection (M0 to 8)			
subjects affected / exposed	5 / 170 (2.94%)	4 / 170 (2.35%)	4 / 171 (2.34%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impetigo (M0 to 8)			
subjects affected / exposed	4 / 170 (2.35%)	0 / 170 (0.00%)	3 / 171 (1.75%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis (M0 to 8)			
subjects affected / exposed	2 / 170 (1.18%)	2 / 170 (1.18%)	3 / 171 (1.75%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection (M0 to 8)			
subjects affected / exposed	3 / 170 (1.76%)	2 / 170 (1.18%)	0 / 171 (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
Otitis media (M0 to 8)			
subjects affected / exposed	3 / 170 (1.76%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acarodermatitis (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	2 / 171 (1.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis (M0 to 8)			

subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (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
Bronchopneumonia (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (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 (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (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
Salmonella sepsis (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (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
Acquired immunodeficiency syndrome (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Extrapulmonary tuberculosis (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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
Hydrocele male infected (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (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
Mastoiditis (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute (M0 to 8)			

subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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
Periorbital abscess (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (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 (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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
Rhinitis (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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 infection (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (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 falciparum infection (M8 to 19)			
subjects affected / exposed	6 / 170 (3.53%)	6 / 170 (3.53%)	14 / 171 (8.19%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia (M8 to 19)			
subjects affected / exposed	5 / 170 (2.94%)	7 / 170 (4.12%)	7 / 171 (4.09%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Upper respiratory tract infection (M8 to 19)			
subjects affected / exposed	7 / 170 (4.12%)	4 / 170 (2.35%)	5 / 171 (2.92%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis (M8 to 19)			

subjects affected / exposed	7 / 170 (4.12%)	6 / 170 (3.53%)	2 / 171 (1.17%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Impetigo (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	3 / 170 (1.76%)	3 / 171 (1.75%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis (M8 to 19)			
subjects affected / exposed	3 / 170 (1.76%)	2 / 170 (1.18%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection (M8 to 19)			
subjects affected / exposed	3 / 170 (1.76%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	2 / 171 (1.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchopneumonia (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	1 / 170 (0.59%)	0 / 171 (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
Nasopharyngitis (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	2 / 171 (1.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired immunodeficiency syndrome (M8 to 19)			

subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dysentery (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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
Pyelonephritis (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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 infection (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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
Pharyngitis (M8 to 19)			

subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (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
Metabolism and nutrition disorders			
Dehydration (M0 to 8)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	0 / 171 (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
Malnutrition (M0 to 8)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malnutrition (M8 to 19)			
subjects affected / exposed	2 / 170 (1.18%)	1 / 170 (0.59%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration (M8 to 19)			
subjects affected / exposed	1 / 170 (0.59%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive (M8 to 19)			
subjects affected / exposed	0 / 170 (0.00%)	0 / 170 (0.00%)	1 / 171 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	GSK 257049 1 Group	GSK 257049 2 Group	Tritanrix™ HepB/Hiberix™ Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	160 / 170 (94.12%)	161 / 170 (94.71%)	164 / 171 (95.91%)
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	11 / 170 (6.47%)	19 / 170 (11.18%)	11 / 171 (6.43%)
occurrences (all)	11	19	11
General disorders and administration site conditions			
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	82 / 170 (48.24%)	97 / 170 (57.06%)	72 / 171 (42.11%)
occurrences (all)	82	97	72
Fever			
alternative assessment type: Systematic			
subjects affected / exposed	102 / 170 (60.00%)	95 / 170 (55.88%)	75 / 171 (43.86%)
occurrences (all)	102	95	75
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	124 / 170 (72.94%)	131 / 170 (77.06%)	118 / 171 (69.01%)
occurrences (all)	124	131	118
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed	68 / 170 (40.00%)	83 / 170 (48.82%)	70 / 171 (40.94%)
occurrences (all)	68	83	70
Pain (post DTPw-HBV/Hib vaccination)			
alternative assessment type: Systematic			
subjects affected / exposed	127 / 170 (74.71%)	133 / 170 (78.24%)	140 / 171 (81.87%)
occurrences (all)	127	133	140
Pain (post Rouvax vaccination)			
alternative assessment type: Systematic			
subjects affected / exposed[1]	52 / 163 (31.90%)	54 / 161 (33.54%)	47 / 159 (29.56%)
occurrences (all)	52	54	47
Pain (post GSK257049 vaccination)			
alternative assessment type: Systematic			
subjects affected / exposed[2]	126 / 170 (74.12%)	116 / 170 (68.24%)	0 / 1 (0.00%)
occurrences (all)	126	116	0
Pain (post Stamaril vaccination)			
alternative assessment type: Systematic			

subjects affected / exposed[3]	2 / 95 (2.11%)	7 / 94 (7.45%)	2 / 94 (2.13%)
occurrences (all)	2	7	2
Swelling (post DTPw-HBV/Hib vaccination)			
alternative assessment type: Systematic			
subjects affected / exposed	47 / 170 (27.65%)	68 / 170 (40.00%)	68 / 171 (39.77%)
occurrences (all)	47	68	68
Swelling (post Rouvax vaccination)			
alternative assessment type: Systematic			
subjects affected / exposed[4]	20 / 163 (12.27%)	21 / 161 (13.04%)	16 / 159 (10.06%)
occurrences (all)	20	21	16
Swelling (post GSK257049 vaccination)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	28 / 170 (16.47%)	44 / 170 (25.88%)	0 / 1 (0.00%)
occurrences (all)	28	44	0
Induration			
subjects affected / exposed	26 / 170 (15.29%)	28 / 170 (16.47%)	29 / 171 (16.96%)
occurrences (all)	26	28	29
Swelling (post Stamaril vaccination)			
subjects affected / exposed	0 / 170 (0.00%)	1 / 170 (0.59%)	0 / 171 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	16 / 170 (9.41%)	21 / 170 (12.35%)	19 / 171 (11.11%)
occurrences (all)	16	21	19
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	21 / 170 (12.35%)	24 / 170 (14.12%)	24 / 171 (14.04%)
occurrences (all)	21	24	24
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	21 / 170 (12.35%)	30 / 170 (17.65%)	24 / 171 (14.04%)
occurrences (all)	21	30	24
Rhinorrhoea			

subjects affected / exposed	19 / 170 (11.18%)	19 / 170 (11.18%)	23 / 171 (13.45%)
occurrences (all)	19	19	23
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	66 / 170 (38.82%)	66 / 170 (38.82%)	65 / 171 (38.01%)
occurrences (all)	66	66	65
Nasopharyngitis			
subjects affected / exposed	53 / 170 (31.18%)	62 / 170 (36.47%)	71 / 171 (41.52%)
occurrences (all)	53	62	71
Gastroenteritis			
subjects affected / exposed	29 / 170 (17.06%)	25 / 170 (14.71%)	32 / 171 (18.71%)
occurrences (all)	29	25	32
Rhinitis			
subjects affected / exposed	16 / 170 (9.41%)	21 / 170 (12.35%)	21 / 171 (12.28%)
occurrences (all)	16	21	21
Pneumonia			
subjects affected / exposed	19 / 170 (11.18%)	11 / 170 (6.47%)	9 / 171 (5.26%)
occurrences (all)	19	11	9
Bronchitis			
subjects affected / exposed	17 / 170 (10.00%)	0 / 170 (0.00%)	21 / 171 (12.28%)
occurrences (all)	17	0	21

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Results are presented as per number of subjects with available results regarding the specified vaccine(s)

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Results are presented as per number of subjects with available results regarding the specified vaccine(s)

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Results are presented as per number of subjects with available results regarding the specified vaccine(s)

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Results are presented as per number of subjects with available results regarding the specified vaccine(s)

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Results are presented as per number of subjects with available results regarding the specified vaccine(s)

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 September 2007	The RTS,S/AS01E candidate malaria vaccine is being developed for the routine immunization of infants and children living in malaria-endemic areas as part of the Expanded Program of Immunization (EPI). The RTS,S/AS01E candidate malaria vaccine consists of sequences of the circumsporozoite (CS) protein and hepatitis B surface antigen (HBsAg) with the proprietary adjuvant AS01E (proprietary liposomes, MPL® and Stimulon® QS21 immunostimulants). The vaccine also induces a strong immune response against hepatitis B. Most previous malaria vaccine studies in children have been conducted with the same antigen, but administered with an adjuvant formulation from the AS02 adjuvant system family which consists of an oil-in-water emulsion, MPL® and QS21. The following table details the various vaccine formulations that have been trialed in humans, are ongoing or are planned for human trials.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported