



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.

Summary

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

Results information

Result version number	v3 (current)
This version publication date	22 November 2020
First version publication date	18 July 2015
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Results have been amended to account for consistency with other registries.

Trial information

Trial identification

Sponsor protocol code	106369
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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 $\geq 37.5^{\circ}\text{C}$, a blood slide was performed to test for malaria 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	Gabon: 220
Country: Number of subjects enrolled	Ghana: 81
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: -

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, 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, Tritanrix TM -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, Hiberix TM
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, 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, 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
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Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix HepB/Hib, 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
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Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix HepB/Hib, 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
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Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix HepB/Hib, 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, 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, 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, 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: This outcome was descriptive; hence no statistical analyses were required.

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

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

End point title	Concentrations of antibodies against hepatitis B (Anti-HB antibodies). ^[2]
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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
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End point timeframe:

At Months 0, 1, 3 and 7

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome was descriptive; hence no statistical analyses were required.

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). ^[3]
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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
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End point timeframe:

At Months 0, 3, 7 and 8

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome was descriptive; hence no statistical analyses were required.

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). ^[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 Tritanrix HepB/Hiberix 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: This outcome was descriptive; hence no statistical analyses were required.

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)			
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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: 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 8 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)	28	24	27	

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.
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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
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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).
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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
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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.
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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
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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. ^[5]
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: [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: Due to different number of vaccine doses administered, the results for the three groups were presented separately.	

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)	1295.2 (1052.1 to 1594.5)		
Anti-measles, Month 8 [N=119;122]	76.2 (73.8 to 78.6)	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. ^[6]
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.	
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: Due to different number of vaccine doses administered, the results for the three groups were presented separately.	

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;62]	5.3 (4.8 to 5.8)	5.9 (5.1 to 6.9)		
Anti-yellow fever, Month 8 [N=46;64]	172.2 (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. ^[7]
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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
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End point timeframe:

At Months 0, 1, 3 and 7

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: Due to different number of vaccine doses administered, the results for the three groups were presented separately.

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. ^[8]
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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 GSK 257049 2 Group.

End point type	Secondary
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End point timeframe:

At Months 0, 3, 7 and 8

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: Due to different number of vaccine doses administered, the results for the three groups were presented separately.

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. ^[9]
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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
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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: Due to different number of vaccine doses administered, the results for the three groups were presented separately.

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. The GSK 257049 vaccine was not administered to subjects from the Tritanrix HepB/Hiberix Group.	
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.
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End point description:

Assessed solicited general symptoms were drowsiness, fever [axillary temperature equal or above (\geq) 37.5 degrees Celsius ($^{\circ}$ 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
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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 \geq 37.5 $^{\circ}$ 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)
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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
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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).
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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
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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

Adverse events information

Timeframe for reporting adverse events:

SAEs: Months [M] 0-19, as specified for each event; Solicited local/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 all/related reported AEs occurrence was not available and is encoded as equal to the number of subjects affected. One subject from GSK 257049 2 Group died due to SAEs (gastroenteritis, severe dehydration), the event was reported late to sponsor. Subject was reported lost to follow up and the death occurred after the last study visit due date.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	13.0

Reporting groups

Reporting group title	GSK 257049 1 Group
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Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix HepB/Hib, 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
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Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix HepB/Hib, 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
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Reporting group description:

Subjects aged 6 to 10 weeks at the time of first vaccination received 3 doses of Tritanrix HepB/Hib, 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	0	3
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 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
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 / 1
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 / 0
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 / 1
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 / 0	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 / 0
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 / 1
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	169 / 170 (99.41%)	169 / 170 (99.41%)	171 / 171 (100.00%)
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 occurrences (all)	47 / 170 (27.65%) 47	68 / 170 (40.00%) 68	68 / 171 (39.77%) 68
Swelling (post Rouvax vaccination) alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	20 / 163 (12.27%) 20	21 / 161 (13.04%) 21	16 / 159 (10.06%) 16
Swelling (post GSK257049 vaccination) alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all)	28 / 170 (16.47%) 28	44 / 170 (25.88%) 44	0 / 1 (0.00%) 0
Induration subjects affected / exposed occurrences (all)	26 / 170 (15.29%) 26	28 / 170 (16.47%) 28	29 / 171 (16.96%) 29
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	16 / 170 (9.41%) 16	21 / 170 (12.35%) 21	19 / 171 (11.11%) 19
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	21 / 170 (12.35%) 21	24 / 170 (14.12%) 24	24 / 171 (14.04%) 24
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	21 / 170 (12.35%) 21	30 / 170 (17.65%) 30	24 / 171 (14.04%) 24
Rhinorrhoea subjects affected / exposed occurrences (all)	19 / 170 (11.18%) 19	19 / 170 (11.18%) 19	23 / 171 (13.45%) 23
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	66 / 170 (38.82%) 66	66 / 170 (38.82%) 66	65 / 171 (38.01%) 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%)	17 / 170 (10.00%)	21 / 171 (12.28%)
occurrences (all)	17	17	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: This analysis was based only on those subjects from the Total Vaccinated cohort who completed symptom sheets.

[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: This analysis was based only on those subjects from the Total Vaccinated cohort who completed symptom sheets.

[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: This analysis was based only on those subjects from the Total Vaccinated cohort who completed symptom sheets.

[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: This analysis was based only on those subjects from the Total Vaccinated cohort who completed symptom sheets.

[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: This analysis was based only on those subjects from the Total Vaccinated cohort who completed symptom sheets.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 September 2007	<p>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.</p> <p>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.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported