Clinical trial results:
A phase 2, open, randomized, controlled, multi-center study to evaluate the safety and immunogenicity of 7 infant immunization schedules of the RTS,S/AS01E candidate vaccine against P. falciparum.

Summary

EudraCT number	2012-005718-20
Trial protocol	Outside EU/EEA
Global end of trial date	23 December 2014

Results information

Result version number	v2
This version publication date	13 August 2016
First version publication date	03 July 2015
Version creation reason	• New data added to full data set Addition of primary and secondary endpoints.

Trial information

Trial identification

Sponsor protocol code	111315

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01231503
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 12937

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 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 April 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1) To describe the safety of 7 infant immunization schedules of RTS,S/AS01E (RTS,S) integrated with an expanded program on immunization (EPI) regimen comprising OPV (oral polio vaccine), BCG (Bacille Calmette Guerin tuberculosis vaccine), DTPwHepB/Hib (Tritanrix HepB/Hib) and measles (Rouvax) with and without a neonatal dose of hepatitis B vaccine (Engerix-B) (HBV) from study start until month 10.
2) To describe the anti-Plasmodium falciparum cir-cumsporozoite (CS) antigen response induced by 7 infant immunization schedules of RTS,S, integrated with an EPI regimen comprising OPV, BCG, DTPwHepB/Hib and measles vaccine, with and without a neonatal dose of hepatitis B vaccine, at 1 month post Dose 3 of RTSS.

Protection of trial subjects:

All subjects were supervised for 60 min after vaccination/product administration with appropriate medical treatment readily available. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines/products. Subjects were followed-up for xx days after the last vaccination/product administration. In addition, this trial was overseen by a Independent data monitoring committee (IDMC) operating under a charter assisted by a Local Safety Monitor (LSM) at each site. The role of the IDMC included the review of the implementation and progress of the study. It provided initial, regular, and closing advice on safety-related issues to GSK Biologicals. The IDMC also reviewed the Protocol and Report and Analysis Plan (RAP) and safety reports. The IDMC was in the capability, if deemed necessary, convene a meeting with, or request further information from the Principal Investigators, the Medical Monitor/Local Safety Monitors and GSK Biologicals' and MVI's designated project representatives at any stage of the study. If applicable, the IDMC was in the capacity to recommend to the sponsor to suspend the enrollment to the trial and/or vaccination across all sites based on their review of safety data arising in this trial or other relevant trials of the same product.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 January 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Malawi: 480
Worldwide total number of subjects	480
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)	240
Infants and toddlers (28 days-23 months)	240
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:

480 subjects were enrolled into the study. Out of these 480 subjects, 479 were vaccinated and 1 was allocated a subject number but was not vaccinated.

Pre-assignment period milestones

Number of subjects started	480
Number of subjects completed	479

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Protocol deviation: 1

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	RTS,S Neo-10-14 Group

Arm description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 14 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S/AS01E, GSK257049
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 14 weeks of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Investigational medicinal product name	Tritanrix HB + Hib
Investigational medicinal product code	Tritanrix HB + Hib
Other name	Tritanrix™HepB/Hib, DTPwHepB/Hib)
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	BCG Vaccines SSI
Investigational medicinal product code	
Other name	Bacille Calmette Guerin tuberculosis vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, via intradermal route in the shoulder.

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

Dosage and administration details:

Subjects received 4 doses of Polio Sabin™ (OPV), administered orally when ≤ 7 days of age and at 6, 10 and 14 weeks of age.

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

Dosage and administration details:

Subjects received one dose of Rouvax™ (Measles), administered at 9 months of age, intramuscularly in the right antero-lateral thigh.

Arm title	RTS,S Neo-10-26 Group

Arm description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S/AS01E, GSK257049
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 26 weeks of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Investigational medicinal product name	Tritanrix HB + Hib
Investigational medicinal product code	Tritanrix HB + Hib
Other name	Tritanrix™HepB/Hib, DTPwHepB/Hib)
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	BCG Vaccines SSI
Investigational medicinal product code	
Other name	Bacille Calmette Guerin tuberculosis vaccine

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

Dosage and administration details:

Subjects received one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, via intradermal route in the shoulder.

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

Dosage and administration details:

Subjects received 4 doses of Polio Sabin™ (OPV), administered orally when ≤ 7 days of age and at 6, 10 and 14 weeks of age.

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

Dosage and administration details:

Subjects received one dose of Rouvax™ (Measles), administered at 9 months of age, intramuscularly in the right antero-lateral thigh.

Arm title	RTS,S 6-10-14 Group

Arm description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 14 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measlesvaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S/AS01E, GSK257049
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 14 weeks of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Investigational medicinal product name	Tritanrix HB + Hib
Investigational medicinal product code	Tritanrix HB + Hib
Other name	Tritanrix™HepB/Hib, DTPwHepB/Hib)
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	BCG Vaccines SSI
Investigational medicinal product code	
Other name	Bacille Calmette Guerin tuberculosis vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤

7 days of age, via intradermal route in the shoulder.

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

Dosage and administration details:

Subjects received 4 doses of Polio Sabin™ (OPV), administered orally when ≤ 7 days of age and at 6, 10 and 14 weeks of age.

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

Dosage and administration details:

Subjects received one dose of Rouvax™ (Measles), administered at 9 months of age, intramuscularly in the right antero-lateral thigh.

Arm title	RTS,S 6-10-26 Group

Arm description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measlesvaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S/AS01E, GSK257049
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Investigational medicinal product name	Tritanrix HB + Hib
Investigational medicinal product code	Tritanrix HB + Hib
Other name	Tritanrix™HepB/Hib, DTPwHepB/Hib)
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	BCG Vaccines SSI
Investigational medicinal product code	
Other name	Bacille Calmette Guerin tuberculosis vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, via intradermal route in the shoulder.

Investigational medicinal product name	Polio Sabin (Oral)
Investigational medicinal product code	OPV
Other name	Polio Sabin™, OPV

Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received 4 doses of Polio Sabin™ (OPV), administered orally when ≤ 7 days of age and at 6, 10 and 14 weeks of age.

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

Dosage and administration details:

Subjects received one dose of Rouvax™ (Measles), administered at 9 months of age, intramuscularly in the right antero-lateral thigh.

Arm title	Engerix-B Neo/RTS,S 6-10-26 Group

Arm description:

Subjects received one dose of EngerixTM-B (HBV) when ≤ 7 days of age followed by 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E and HBV vaccines were administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S/AS01E, GSK257049
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Investigational medicinal product name	Tritanrix HB + Hib
Investigational medicinal product code	Tritanrix HB + Hib
Other name	Tritanrix™HepB/Hib, DTPwHepB/Hib)
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	BCG Vaccines SSI
Investigational medicinal product code	
Other name	Bacille Calmette Guerin tuberculosis vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, via intradermal route in the shoulder.

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

Dosage and administration details:

Subjects received 4 doses of Polio Sabin™ (OPV), administered orally when ≤ 7 days of age and at 6, 10 and 14 weeks of age.

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

Dosage and administration details:

Subjects received one dose of Rouvax™ (Measles), administered at 9 months of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	Engerix™-B Junior
Investigational medicinal product code	HBV Paediatric 10
Other name	EngerixTM-B , HBV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of EngerixTM-B (HBV) when ≤ 7 days of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Arm title	RTS,S 10-14-26 Group

Arm description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 10, 14 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S/AS01E, GSK257049
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 10, 14 and 26 weeks of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Investigational medicinal product name	Tritanrix HB + Hib
Investigational medicinal product code	Tritanrix HB + Hib
Other name	Tritanrix™HepB/Hib, DTPwHepB/Hib)
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	BCG Vaccines SSI
Investigational medicinal product code	
Other name	Bacille Calmette Guerin tuberculosis vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, via intradermal route in the shoulder.

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

Dosage and administration details:

Subjects received 4 doses of Polio Sabin™ (OPV), administered orally when ≤ 7 days of age and at 6, 10 and 14 weeks of age.

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

Dosage and administration details:

Subjects received one dose of Rouvax™ (Measles), administered at 9 months of age, intramuscularly in the right antero-lateral thigh.

Arm title	RTS,S 14-26-9M Group

Arm description:

Subjects received 3 doses of RTS,S/AS01E (or GSK257049) at 14 and 26 weeks of age and at 9 months of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when below ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Arm type	Experimental
Investigational medicinal product name	Candidate Plasmodium falciparum malaria vaccine
Investigational medicinal product code	RTS,S+AS01E
Other name	RTS,S/AS01E, GSK257049
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 14 and 26 weeks of age and at 9 months of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Investigational medicinal product name	Tritanrix HB + Hib
Investigational medicinal product code	Tritanrix HB + Hib
Other name	Tritanrix™HepB/Hib, DTPwHepB/Hib)
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	BCG Vaccines SSI
Investigational medicinal product code	
Other name	Bacille Calmette Guerin tuberculosis vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, via intradermal route in the shoulder.

Investigational medicinal product name	Polio Sabin (Oral)
Investigational medicinal product code	OPV
Other name	Polio Sabin™, OPV

Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received 4 doses of Polio Sabin™ (OPV), administered orally when ≤ 7 days of age and at 6, 10 and 14 weeks of age.

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

Dosage and administration details:

Subjects received one dose of Rouvax™ (Measles), administered at 9 months of age, intramuscularly in the right antero-lateral thigh.

Arm title	Engerix-B Neo Group

Arm description:

Subjects in this group received one dose of EngerixTM-B (HBV) ≤ 7 days of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when below ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The HBV vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Arm type	Active comparator
Investigational medicinal product name	Engerix™-B Junior
Investigational medicinal product code	HBV Paediatric 10
Other name	EngerixTM-B , HBV
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of EngerixTM-B (HBV) when ≤ 7 days of age, administered intramuscularly (IM) in the left antero-lateral thigh.

Investigational medicinal product name	Tritanrix HB + Hib
Investigational medicinal product code	Tritanrix HB + Hib
Other name	Tritanrix™HepB/Hib, DTPwHepB/Hib)
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, intramuscularly in the right antero-lateral thigh.

Investigational medicinal product name	BCG Vaccines SSI
Investigational medicinal product code	
Other name	Bacille Calmette Guerin tuberculosis vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, via intradermal route in the shoulder.

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

Dosage and administration details:

Subjects received 4 doses of Polio Sabin™ (OPV), administered orally when ≤ 7 days of age and at 6, 10

and 14 weeks of age.

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

Dosage and administration details:

Subjects received one dose of Rouvax™ (Measles), administered at 9 months of age, intramuscularly in the right antero-lateral thigh.

Number of subjects in period 1[1]	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group
Started	60	59	60
Completed	46	46	48
Not completed	14	13	12
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	6	3	3
Adverse event, non-fatal	-	-	-
Lost to follow-up	8	10	8
Protocol deviation	-	-	1

Number of subjects in period 1[1]	RTS,S 6-10-26 Group	Engerix-B Neo/RTS,S 6-10-26	RTS,S 10-14-26 Group
Started	60	60	60
Completed	52	50	44
Not completed	8	10	16
Adverse event, serious fatal	1	-	1
Consent withdrawn by subject	1	3	5
Adverse event, non-fatal	-	-	1
Lost to follow-up	5	7	9
Protocol deviation	1	-	-

Number of subjects in period 1[1]	RTS,S 14-26-9M Group	Engerix-B Neo Group
Started	60	60
Completed	53	52
Not completed	7	8
Adverse event, serious fatal	-	-
Consent withdrawn by subject	1	2
Adverse event, non-fatal	-	-
Lost to follow-up	6	6
Protocol deviation	-	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 480 subjects were enrolled into the study. Out of these 480 subjects, 479 were vaccinated and 1 was allocated a subject number but was not vaccinated

Reporting groups

Reporting group title	RTS,S Neo-10-14 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 14 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S Neo-10-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 6-10-14 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 14 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measlesvaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 6-10-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measlesvaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	Engerix-B Neo/RTS,S 6-10-26 Group

Reporting group description:

Subjects received one dose of EngerixTM-B (HBV) when ≤ 7 days of age followed by 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E and HBV vaccines were administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 10-14-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 10, 14 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10

and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 14-26-9M Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (or GSK257049) at 14 and 26 weeks of age and at 9 months of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when below ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	Engerix-B Neo Group

Reporting group description:

Subjects in this group received one dose of EngerixTM-B (HBV) ≤ 7 days of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when below ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The HBV vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group
Number of subjects	60	59	60
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: days			
arithmetic mean	0.4	0.4	0.2
standard deviation	± 1.1	± 1.2	± 1
Gender categorical Units: Subjects			
Female	30	27	32
Male	30	32	28

Reporting group values	RTS,S 6-10-26 Group	Engerix-B Neo/RTS,S 6-10-26	RTS,S 10-14-26 Group
Number of subjects	60	60	60
Age categorical Units: Subjects			
In utero			

Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: days			
arithmetic mean	0.2	0.5	0.2
standard deviation	± 0.8	± 1.4	± 0.8
Gender categorical			
Units: Subjects			
Female	25	29	31
Male	35	31	29

Reporting group values	RTS,S 14-26-9M Group	Engerix-B Neo Group	Total
Number of subjects	60	60	479
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)			0
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: days			
arithmetic mean	0.2	0.4	
standard deviation	± 0.9	± 1.2	-
Gender categorical			
Units: Subjects			
Female	36	32	242
Male	24	28	237

End points

End points reporting groups

Reporting group title	RTS,S Neo-10-14 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 14 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S Neo-10-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 6-10-14 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 14 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measlesvaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 6-10-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measlesvaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	Engerix-B Neo/RTS,S 6-10-26 Group

Reporting group description:

Subjects received one dose of EngerixTM-B (HBV) when ≤ 7 days of age followed by 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E and HBV vaccines were administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 10-14-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 10, 14 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10

and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 14-26-9M Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (or GSK257049) at 14 and 26 weeks of age and at 9 months of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when below ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	Engerix-B Neo Group

Reporting group description:

Subjects in this group received one dose of EngerixTM-B (HBV) ≤ 7 days of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when below ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The HBV vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

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

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

End point description:

An SAE is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or may evolve into one of the outcomes listed above. "Any" is defined an incidence of a SAE regardless of intensity/severity.

End point type	Primary

End point timeframe:

From study start at Month 0 up to Month 10

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	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	60
Units: Subjects				
SAEs to Month 10	5	4	5	7

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	60
Units: Subjects				
SAEs to Month 10	5	10	4	3

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations of antibodies against circumsporozoite protein of Plasmodium falciparum (anti-CS antibodies)

End point title	Concentrations of antibodies against circumsporozoite protein of Plasmodium falciparum (anti-CS antibodies)[2]

End point description:

Anti-CS antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA) and presented as geometric mean concentrations (GMCs) expressed in ELISA units per milliliter (EL.U/mL). The assay cut-off was the seropositivity cut-off value of greater than or equal to (≥) 0.5 EL.U/mL. Results will be posted when they become available.

End point type	Primary

End point timeframe:

At 1 month post Dose 3 of RTS,S/AS01E

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	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	42	45	43
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-CS, Screening [N=43,42,45,43,45,42,51,45]	0.5 (0.4 to 7)	0.4 (0.3 to 0.5)	0.4 (0.3 to 0.5)	0.4 (0.3 to 0.5)
Anti-CS, PIII(M4) [N=30,32,31,37,39,0,0,36]	33.6 (18.5 to 61.3)	72.8 (44.6 to 118.7)	112.2 (76 to 165.8)	99.7 (61.3 to 162)
Anti-CS PIV(M5) [N=47,0,45,0,0,44,0,48]	128.2 (92.2 to 178.2)	0 (0 to 0)	218.3 (160.1 to 297.6)	0 (0 to 0)
Anti-CS, PV(M7) [N=0,43,0,46,43,42,36,47]	0 (0 to 0)	136.6 (93 to 200.7)	0 (0 to 0)	156.5 (100.4 to 244)
Anti-CS, PVI(M10) [N=39,37,36,40,39,38,47,40]	13.8 (8.5 to 22.6)	39.5 (22.4 to 69.6)	30.1 (18.8 to 48.2)	44.2 (23.8 to 82.2)

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	42	51	45
Units: EL.U/mL				

geometric mean (confidence interval 95%)				
Anti-CS, Screening [N=43,42,45,43,45,42,51,45]	0.4 (0.3 to 0.6)	0.4 (0.3 to 0.5)	0.4 (0.3 to 0.5)	0.5 (0.4 to 0.7)
Anti-CS, PIII(M4) [N=30,32,31,37,39,0,0,36]	88 (55.4 to 139.8)	0 (0 to 0)	0 (0 to 0)	0.3 (0.3 to 0.3)
Anti-CS PIV(M5) [N=47,0,45,0,0,44,0,48]	0 (0 to 0)	167.6 (133.2 to 210.9)	0 (0 to 0)	0.3 (0.3 to 0.3)
Anti-CS, PV(M7) [N=0,43,0,46,43,42,36,47]	170.6 (170.6 to 254.1)	392.6 (323.3 to 476.7)	141.7 (97 to 207.1)	0.3 (0.3 to 0.3)
Anti-CS, PVI(M10) [N=39,37,36,40,39,38,47,40]	43.3 (24.6 to 76)	121 (89.4 to 163.7)	269.9 (183.3 to 397.5)	0.3 (0.2 to 0.4)

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. "Any" is defined an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination. Please note that, for this outcome measure, analysis was performed only on subjects with at least one administered dose of RTS,S/AS01E and/or DTPwHepB/Hib for the Engerix-B Neo Group.

End point type	Secondary

End point timeframe:

During the 30-day (Days 0-29) post vaccination period following 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	54	57
Units: Subjects				
Unsolicited AEs	36	35	28	29

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	52	57	52
Units: Subjects				
Unsolicited AEs	35	36	47	31

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An SAE is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or may evolve into one of the outcomes listed above. "Any" is defined an incidence of a SAE regardless of intensity/severity.

End point type	Secondary

End point timeframe:

From study start at Month 0 up to Month 18 (corresponding data lock point =23 March 2015)

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	60
Units: Subjects				
SAEs to Month 18	7	5	6	9

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	60
Units: Subjects				
SAEs to Month 18	8	12	5	4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with biochemical abnormalities, for the alanine aminotransferase (ALT) parameter

End point title	Number of subjects reported with biochemical abnormalities, for the alanine aminotransferase (ALT) parameter

End point description:

This outcome measure concerns biochemical abnormalities, for the alanine aminotransferase (ALT) parameter. Subjects' levels were assessed as either normal, Grade 1, Grade 2, Grade 3, Grade 4, Missing or Out of range (OOR). Normal ALT level was defined as ALT< 60 International units per milliliter (IU/mL). Grade 1 ALT level was defined as 1.1 to 2.5 times the upper limit of normal (ULN). Grade 2 ALT level was defined as 2.6 to 5.0 times the ULN. Grade 3 ALT level was defined as 5.1 to 10.0 times the ULN. Grade 4 ALT level was defined as > 10.0 times the ULN.

End point type	Secondary

End point timeframe:

At screening (SCR), at Study Day 6 (D6), at 6 days post Study Week 6 (W6+6D), at 6 days post Study Week 10 (W10+6D), at 6 days post Study Week 14 (W14+6D), at Month 5 (M5), at Month 7 (M7) and at Month 10 (M10).

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	59	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	56	55	0	0
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	1	0	0	0
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	1	2	0	0
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	0	0	51	55
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	2	2
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	0	0	0

W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0
W14+6D, Normal (N=0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 1 (N=0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 2 (N=0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 4 (N=0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;51)	48	0	49	0
M5, Grade 1 (N=51;0;50;0;0;0;51)	1	0	0	0
M5, Grade 2 (N=51;0;50;0;0;0;51)	0	0	0	0
M5, Grade 3 (N=51;0;50;0;0;0;51)	0	0	0	0
M5, Grade 4 (N=51;0;50;0;0;0;51)	0	0	0	0
M5, Missing (N=51;0;50;0;0;0;51)	2	0	1	0
M5, OOR (N=51;0;50;0;0;0;51)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	0	49	0	52
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	2
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 1 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 2 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 4 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, OOR (N=0;0,0;0;0;0;53;52)	0	0	0	0

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	60	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0

SCR, OOR (N=60;59,60;60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	0	0	0	57
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	1
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	55	52	0	0
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	2	2	0	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	50	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	1	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	1	0	0
W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	56	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	1	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;0;51)	0	0	0	50
M5, Grade 1 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 2 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 3 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 4 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Missing (N=51;0;50;0;0;0;0;51)	0	0	0	1
M5, OOR (N=51;0;50;0;0;0;0;51)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	52	47	0	52
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	0	0	0

M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	1	0	0	0
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;53;52)	0	0	51	48
M10, Grade 1 (N=0;0,0;0;0;0;53;52)	0	0	0	1
M10, Grade 2 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 4 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;53;52)	0	0	2	3
M10, OOR (N=0;0,0;0;0;0;53;52)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with biochemical abnormalities, for the creatinine (CREA) parameter

End point title	Number of subjects reported with biochemical abnormalities, for the creatinine (CREA) parameter

End point description:

This outcome measure concerns biochemical abnormalities, for the creatinine (CREA) parameter. Subjects' levels were assessed as either normal, Grade 1, Grade 2, Grade 3, Grade 4, Missing or Out of range (OOR). Normal CREA level was defined as CREA ≤ 106, 88 and 71 micromoles per liter (µmol/L) for subjects 1, 2 or ≥ 2 days of age, respectively. Grade 1 CREA level was defined as 1.1 to 1.3 times the upper limit of normal (ULN). Grade 2 CREA level was defined as 1.4 to 1.8 times the ULN. Grade 3 CREA level was defined as 1.9 to 3.4 times the ULN. Grade 4 CREA level was defined as ≥ 3.5 times the ULN.

End point type	Secondary

End point timeframe:

At screening (SCR), at Study Day 6 (D6), at 6 days post Study Week 6 (W6+6D), at 6 days post Study Week 10 (W10+6D), at 6 days post Study Week 14 (W14+6D), at Month 5 (M5), at Month 7 (M7) and at Month 10 (M10).

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	59	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0

SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	55	55	0	0
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	3	2	0	0
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	0	0	53	57
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0
W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;0;51)	50	0	50	0
M5, Grade 1 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 2 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 3 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 4 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Missing (N=51;0;50;0;0;0;0;51)	1	0	0	0
M5, OOR (N=51;0;50;0;0;0;0;51)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	0	49	0	52
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	0	0	0

M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	2
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 1 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 2 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Grade 4 (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;53;52)	0	0	0	0
M10, OOR (N=0;0,0;0;0;0;53;52)	0	0	0	0

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	60	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	0	0	0	56
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	0	0	0	2
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	57	53	0	0
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	1	0	0
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	51	0	0

W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	1	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0
W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	57	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;0;51)	0	0	0	50
M5, Grade 1 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 2 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 3 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Grade 4 (N=51;0;50;0;0;0;0;51)	0	0	0	0
M5, Missing (N=51;0;50;0;0;0;0;51)	0	0	0	1
M5, OOR (N=51;0;50;0;0;0;0;51)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	53	47	0	52
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;0;53;52)	0	0	52	52
M10, Grade 1 (N=0;0,0;0;0;0;0;53;52)	0	0	0	0
M10, Grade 2 (N=0;0,0;0;0;0;0;53;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;0;53;52)	0	0	0	0
M10, Grade 4 (N=0;0,0;0;0;0;0;53;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;0;53;52)	0	0	1	0
M10, OOR (N=0;0,0;0;0;0;0;53;52)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with haematological abnormalities, for the haemoglobin (HAE) parameter

End point title	Number of subjects reported with haematological

	abnormalities, for the haemoglobin (HAE) parameter

End point description:

This outcome measure concerns haematological abnormalities, for the haemoglobin (HAE) parameter. Subjects' levels were assessed as either normal, Grade (G) 1, G2, G3, G4, Missing or Out of range (OOR). Normal HAE level was defined as HAE > 13.0 and 10.5 grams per deciliter (g/dL) for subjects aged 1 to 21 and 22 to 35 days respectively. Grades were defined as follows: 1) In subjects aged 1 to 21 days: G1 = HAE as 12.0 to 13.0 g/dL, G2 = HAE as 10.0 to 11.9 g/dL, G3 = HAE as 9.0 to 9.9 g/dL, G4 = HAE < 9.0 g/dL; 2) In subjects aged 22 to 35 days: G1 = HAE as 9.5 to 10.5 g/dL, G2 = HAE as 8.0 to 9.4 g/dL, G3 = HAE as 7.0 to 7.9 g/dL, G4 = HAE < 7.0 g/dL; 3) In subjects aged 36 to 56 days: G1 = HAE as 8.5 to 9.4 g/dL, G2 = HAE as 7.0 to 8.4 g/dL, G3 = HAE as 6.0 to 6.9 g/dL, G4 = HAE < 6.0 g/dL; 4) In subjects aged ≥ 57 days: G1 = HAE as 10.0 to 10.9 g/dL, G2 = HAE as 9.0 to 9.9 g/dL, G3 = HAE as 7.0 to 8.9 g/dL, G4 = HAE < 7.0 g/dL.

End point type	Secondary

End point timeframe:

At screening (SCR), at Study Day 6 (D6), at 6 days post Study Week 6 (W6+6D), at 6 days post Study Week 10 (W10+6D), at 6 days post Study Week 14 (W14+6D), at Month 5 (M5), at Month 7 (M7) and at Month 10 (M10).

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	59	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	51	47	0	0
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	1	5	0	0
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	5	4	0	0
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	1	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	1	0	0	0
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	0	0	43	50
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	0	0	5	5
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	2	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	1	1
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	2	1
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0

W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0
W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;0;52)	25	0	23	0
M5, Grade 1 (N=51;0;50;0;0;0;0;52)	16	0	16	0
M5, Grade 2 (N=51;0;50;0;0;0;0;52)	7	0	10	0
M5, Grade 3 (N=51;0;50;0;0;0;0;52)	3	0	0	0
M5, Grade 4 (N=51;0;50;0;0;0;0;52)	0	0	1	0
M5, Missing (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, OOR (N=51;0;50;0;0;0;0;52)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	0	17	0	15
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	0	15	0	18
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	11	0	13
M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	6	0	7
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	1
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 1 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 2 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 4 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, OOR (N=0;0,0;0;0;0;0;54;52)	0	0	0	0

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	60
Units: Subjects				

SCR, Normal (N=60;59,60;60;60;60;60;60)	60	60	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	0	0	0	48
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	0	0	0	3
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	0	0	0	3
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	3
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	0	0	1
D6, Missing (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	48	45	0	0
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	7	6	0	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	2	2	0	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	1	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	18	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	15	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	10	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	7	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	2	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0
W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	25	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	21	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	9	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	2	0
W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0

M5, Normal (N=51;0;50;0;0;0;0;52)	0	0	0	20
M5, Grade 1 (N=51;0;50;0;0;0;0;52)	0	0	0	24
M5, Grade 2 (N=51;0;50;0;0;0;0;52)	0	0	0	6
M5, Grade 3 (N=51;0;50;0;0;0;0;52)	0	0	0	2
M5, Grade 4 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Missing (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, OOR (N=51;0;50;0;0;0;0;52)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	12	6	0	10
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	26	15	0	23
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	11	18	0	12
M7, Grade 3 (N=0;49;0;54;53;47;0;52)	4	8	0	6
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	1
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;0;54;52)	0	0	15	8
M10, Grade 1 (N=0;0,0;0;0;0;0;54;52)	0	0	19	16
M10, Grade 2 (N=0;0,0;0;0;0;0;54;52)	0	0	12	17
M10, Grade 3 (N=0;0,0;0;0;0;0;54;52)	0	0	8	11
M10, Grade 4 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, OOR (N=0;0,0;0;0;0;0;54;52)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with haematological abnormalities, for the platelets (PLA) parameter

End point title	Number of subjects reported with haematological abnormalities, for the platelets (PLA) parameter

End point description:

This outcome measure concerns haematological abnormalities, for the platelets (PLA) parameter. Subjects' levels were assessed as either normal, Grade (G) 1, G2, G3, G4, Missing or Out of range (OOR). Normal PLA level was defined as > 125 x 109 PLA per liter (Billions PLA/L). Grade 1 PLA level was defined as 100 to 125 Billions PLA/L. Grade 2 PLA level was defined as 50 to 99 Billions PLA/L. Grade 3 PLA level was defined as 25 to 49 Billions PLA/L. Grade 4 PLA level was defined as < 25 Billions PLA/L.

End point type	Secondary

End point timeframe:

At screening (SCR), at Study Day 6 (D6), at 6 days post Study Week 6 (W6+6D), at 6 days post Study Week 10 (W10+6D), at 6 days post Study Week 14 (W14+6D), at Month 5 (M5), at Month 7 (M7) and at Month 10 (M10).

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	59	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	54	55	0	0
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	3	1	0	0
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	1	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	1	0	0	0
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	0	0	47	55
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	0	0	2	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	2	1
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	2	1
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0
W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	0	0

W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;0;52)	51	0	46	0
M5, Grade 1 (N=51;0;50;0;0;0;0;52)	0	0	1	0
M5, Grade 2 (N=51;0;50;0;0;0;0;52)	0	0	1	0
M5, Grade 3 (N=51;0;50;0;0;0;0;52)	0	0	1	0
M5, Grade 4 (N=51;0;50;0;0;0;0;52)	0	0	1	0
M5, Missing (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, OOR (N=51;0;50;0;0;0;0;52)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	0	49	0	53
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	1
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 1 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 2 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 4 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, OOR (N=0;0,0;0;0;0;0;54;52)	0	0	0	0

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	60	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	0	0	0	51
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	0	0	0	5
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	0	0	0	2
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	0	0	0	0

D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	57	53	0	0
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	1	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	47	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	2	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	1	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	2	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0
W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	57	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;0;52)	0	0	0	51
M5, Grade 1 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Grade 2 (N=51;0;50;0;0;0;0;52)	0	0	0	1
M5, Grade 3 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Grade 4 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Missing (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, OOR (N=51;0;50;0;0;0;0;52)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	51	45	0	50
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	2	1	0	1
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	0	0	1
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	1	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;0;54;52)	0	0	53	51
M10, Grade 1 (N=0;0,0;0;0;0;0;54;52)	0	0	1	0
M10, Grade 2 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;0;54;52)	0	0	0	1

M10, Grade 4 (N=0;0,0;0;0;0;54;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;54;52)	0	0	0	0
M10, OOR (N=0;0,0;0;0;0;54;52)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with haematological abnormalities, for the white blood cells (WBC) parameter

End point title	Number of subjects reported with haematological abnormalities, for the white blood cells (WBC) parameter

End point description:

This outcome measure concerns haematological abnormalities, for the white blood cells (WBC) parameter. Subjects' levels were assessed as either normal, Grade 1, Grade 2, Grade 3, Grade 4, Missing or Out of range (OOR). Normal WBC level was defined as > 2.5 x 109 WBC per liter (Billions WBC/L). Grade 1 WBC level was defined as 2.0 to 2.5 Billions WBC/L. Grade 2 WBC level was defined as 1.5 to 1.999 Billions WBC/L. Grade 3 WBC level was defined as 1.0 to 1.499 Billions WBC/L. Grade 4 WBC level was defined as < 1.0 Billions WBC/L.

End point type	Secondary

End point timeframe:

At screening (SCR), at Study Day 6 (D6), at 6 days post Study Week 6 (W6+6D), at 6 days post Study Week 10 (W10+6D), at 6 days post Study Week 14 (W14+6D), at Month 5 (M5), at Month 7 (M7) and at Month 10 (M10).

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	59	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	57	57	0	0
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	1	0	0	0
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0

W6+6D, Normal (N=0;0;53;57;57;54;0;0)	0	0	50	56
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	3	1
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0
W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;0;52)	51	0	50	0
M5, Grade 1 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Grade 2 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Grade 3 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Grade 4 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Missing (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, OOR (N=51;0;50;0;0;0;0;52)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	0	49	0	53
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	1
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 1 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 2 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 4 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0

M10, Missing (N=0;0,0;0;0;0;54;52)	0	0	0	0
M10, OOR (N=0;0,0;0;0;0;54;52)	0	0	0	0

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	60
Units: Subjects				
SCR, Normal (N=60;59,60;60;60;60;60;60)	60	60	60	60
SCR, Grade 1 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 2 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 3 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Grade 4 (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, Missing (N=60;59,60;60;60;60;60;60)	0	0	0	0
SCR, OOR (N=60;59,60;60;60;60;60;60)	0	0	0	0
D6, Normal (N=58;57;0;0;0;0;0;58)	0	0	0	58
D6, Grade 1 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 2 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 3 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Grade 4 (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, Missing (N=58;57;0;0;0;0;0;58)	0	0	0	0
D6, OOR (N=58;57;0;0;0;0;0;58)	0	0	0	0
W6+6D, Normal (N=0;0;53;57;57;54;0;0)	57	54	0	0
W6+6D, Grade 1 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 2 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 3 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Grade 4 (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, Missing (N=0;0;53;57;57;54;0;0)	0	0	0	0
W6+6D, OOR (N=0;0;53;57;57;54;0;0)	0	0	0	0
W10+6D, Normal (N=0;0;0;0;0;52;0;0)	0	50	0	0
W10+6D, Grade 1 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 2 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 3 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Grade 4 (N=0;0;0;0;0;52;0;0)	0	0	0	0
W10+6D, Missing (N=0;0;0;0;0;52;0;0)	0	2	0	0
W10+6D, OOR (N=0;0;0;0;0;52;0;0)	0	0	0	0

W14+6D, Normal (N=0;0;0;0;0;0;57;0)	0	0	57	0
W14+6D, Grade 1 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 2 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 3 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Grade 4 (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, Missing (N=0;0;0;0;0;0;57;0)	0	0	0	0
W14+6D, OOR (N=0;0;0;0;0;0;57;0)	0	0	0	0
M5, Normal (N=51;0;50;0;0;0;0;52)	0	0	0	52
M5, Grade 1 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Grade 2 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Grade 3 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Grade 4 (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, Missing (N=51;0;50;0;0;0;0;52)	0	0	0	0
M5, OOR (N=51;0;50;0;0;0;0;52)	0	0	0	0
M7, Normal (N=0;49;0;54;53;47;0;52)	53	47	0	51
M7, Grade 1 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 2 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Grade 3 (N=0;49;0;54;53;47;0;52)	0	0	0	1
M7, Grade 4 (N=0;49;0;54;53;47;0;52)	0	0	0	0
M7, Missing (N=0;49;0;54;53;47;0;52)	0	0	0	1
M7, OOR (N=0;49;0;54;53;47;0;52)	0	0	0	0
M10, Normal (N=0;0,0;0;0;0;0;54;52)	0	0	54	52
M10, Grade 1 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 2 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 3 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Grade 4 (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, Missing (N=0;0,0;0;0;0;0;54;52)	0	0	0	0
M10, OOR (N=0;0,0;0;0;0;0;54;52)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of antibodies against circumsporozoite protein of Plasmodium falciparum (anti-CS antibodies)

End point title	Concentrations of antibodies against circumsporozoite protein of Plasmodium falciparum (anti-CS antibodies)

End point description:

Anti-CS antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA) and presented as geometric mean concentrations (GMCs) expressed in ELISA units per milliliter (EL.U/mL). The assay cut-off was the seropositivity cut-off value of greater than or equal to (≥) 0.5 EL.U/mL. Results will be posted when they become available.

End point type	Secondary

End point timeframe:

At Screening (SCR), at Month 5 (M5), at Month 7 (M7) and at Month 10 (M10), according to the vaccination scheduling

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[3]	0[4]	0[5]	0[6]
Units: EL.U/mL				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[3] - Validated anti-CS results were not available at the time of writing.

[4] - Validated anti-CS results were not available at the time of writing.

[5] - Validated anti-CS results were not available at the time of writing.

[6] - Validated anti-CS results were not available at the time of writing.

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	0[8]	0[9]	0[10]
Units: EL.U/mL				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[7] - Validated anti-CS results were not available at the time of writing.

[8] - Validated anti-CS results were not available at the time of writing.

[9] - Validated anti-CS results were not available at the time of writing.

[10] - Validated anti-CS results were not available at the time of writing.

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Hepatitis B surface antibody (anti-HBs) concentrations.

End point title	Anti-Hepatitis B surface antibody (anti-HBs) concentrations.

End point description:

Concentrations, by enzyme-linked immunosorbent assay (ELISA), were presented as geometric mean concentrations (GMCs), and expressed in milli-international units per milliliter (mIU/mL). The seropositivity and seroprotection cut-offs were than or equal to (≥) 6.2 and 10 mIU/mL, respectively.

End point type	Secondary

End point timeframe:

At Screening (SCR), at Month 5 (M5), at Month 7 (M7) and at Month 10 (M10), according to the vaccination scheduling.

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	37	37	38
Units: mIU/mL				
geometric mean (confidence interval 95%)				
SCR (N=27;25;32;34;32;32;37;31)	10.7 (4.2 to 27.3)	22.2 (6.6 to 74.6)	9.9 (4.4 to 22)	9.5 (4.4 to 20.6)
M5 (N=25;0;17;0;0;0;0;22)	6479 (3858.9 to 10878.2)	0 (0 to 0)	3831.6 (1783.4 to 8232.3)	0 (0 to 0)
M7 (N=0;35;0;37;30;34;0;38)	0 (0 to 0)	23218.5 (16670.1 to 32339.2)	0 (0 to 0)	29839.9 (20731.1 to 42951)
M10 (N=33;37;37;38;37;31;37;34)	2949.5 (2040.5 to 4263.4)	9630.8 (6472.2 to 14330.9)	3135 (2287.6 to 4296.2)	8581.8 (5974.8 to 12326.5)

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	34	37	38
Units: mIU/mL				
geometric mean (confidence interval 95%)				
SCR (N=27;25;32;34;32;32;37;31)	17.2 (7.1 to 41.8)	12.6 (4.9 to 32)	38.6 (13.6 to 109.5)	22.6 (8.5 to 59.8)
M5 (N=25;0;17;0;0;0;0;22)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	640.7 (381.3 to 1076.7)
M7 (N=0;35;0;37;30;34;0;38)	34589.1 (21299.2 to 56171.6)	44472.4 (31305.5 to 63177.1)	0 (0 to 0)	430.1 (277.8 to 666)
M10 (N=33;37;37;38;37;31;37;34)	12084.3 (8211.6 to 17783.5)	13360.1 (8195.5 to 21779.4)	75018 (54992.1 to 102336.5)	139.5 (77.2 to 252.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-diphtheria (Anti-D) and anti-tetanus toxoids (anti-TT) antibody concentrations

End point title	Anti-diphtheria (Anti-D) and anti-tetanus toxoids (anti-TT) antibody concentrations

End point description:

Anti-D and anti-TT antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in International units per milliliter (IU/mL), and tabulated. The seropositivity cut-off for the assay was ≥ 0.1 IU/mL.

End point type	Secondary

End point timeframe:

At Month 5

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	46	45	48
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D	3.1 (2.2 to 4.5)	3.9 (2.9 to 5.3)	3.2 (2.5 to 4)	4 (3.2 to 5.1)
Anti-TT	3.5 (2.6 to 4.6)	3.2 (2.3 to 4.4)	3.7 (2.8 to 4.8)	2.8 (2.2 to 3.7)

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	44	54	47
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D	3.6 (2.7 to 4.8)	4.3 (3.2 to 5.8)	4.3 (3.4 to 5.5)	4.6 (3.7 to 5.6)
Anti-TT	3.3 (2.4 to 4.4)	3.3 (2.4 to 4.6)	3.5 (2.6 to 4.6)	4.6 (3.5 to 6)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polyribosyl ribitol phosphate (anti-PRP) antibody concentrations

End point title	Anti-polyribosyl ribitol phosphate (anti-PRP) antibody concentrations

End point description:

Anti-PRP antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter (g/mL), and tabulated. The seroprotection cut-off for the assay for the purpose of this endpoint was ≥ 0.15 g/mL.

End point type	Secondary

End point timeframe:

At Month 5

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	44	44	48
Units: µg/mL				
geometric mean (confidence interval 95%)				

Anti-PRP	6.8 (4.5 to 10.3)	11.1 (7.5 to 16.5)	11.4 (7.3 to 17.8)	13.6 (9.6 to 19.3)

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	43	52	47
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP	10.9 (7.4 to 16)	11 (7.1 to 16.9)	15.6 (10.6 to 22.8)	13.8 (9.7 to 19.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers

End point title	Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers

End point description:

Anti-Polio 1, 2 and 3 antibody titers were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seroprotection cut-off for the assay was ≥ 8. Results will be posted when they become available.

End point type	Secondary

End point timeframe:

At Month 5

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[11]	0[12]	0[13]	0[14]
Units: Titers				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[11] - Validated anti-Polio results were not available at the time of writing.

[12] - Validated anti-Polio results were not available at the time of writing.

[13] - Validated anti-Polio results were not available at the time of writing.

[14] - Validated anti-Polio results were not available at the time of writing.

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[15]	0[16]	0[17]	0[18]
Units: Titers				

geometric mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[15] - Validated anti-Polio results were not available at the time of writing.

[16] - Validated anti-Polio results were not available at the time of writing.

[17] - Validated anti-Polio results were not available at the time of writing.

[18] - Validated anti-Polio results were not available at the time of writing.

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of antibodies against acellular B-pertussis (BPT)

End point title	Concentrations of antibodies against acellular B-pertussis (BPT)

End point description:

Concentrations of anti-BPT antibodies were determined by enzyme-linked immunosorbent assay (ELISA) and expressed as geometric mean concentrations (GMCs), in ELISA units per milliliter (EL.U/mL). The cut-off of the assay was the seropositivity cut-off value of greater than or equal to (≥) 15 EL.U/mL.

End point type	Secondary

End point timeframe:

At Month 5

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	42	41	46
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT	82.9 (69.9 to 98.4)	102.3 (84.9 to 123.4)	86.7 (72.5 to 103.7)	81.2 (66.7 to 98.8)

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	50	41
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT	99.2 (82.6 to 119.1)	86.1 (71.7 to 103.4)	91 (75.9 to 109)	109.8 (89.7 to 134.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of antibodies against measles antigens

End point title	Concentrations of antibodies against measles antigens[19]

End point description:

The seropositivity cut-off for the assay was an anti-measles antibody (Anti-Measles Ab) concentration ≥ 150 milli-international units per millilitre (mIU/mL). Please note that this outcome measure was only assessed in subjects in the RTS,S 14-26-9M and Engerix-B Neo groups.

End point type	Secondary

End point timeframe:

At Month 10

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Please note that this outcome measure was only assessed in subjects in the RTS,S 14-26-9M and Engerix-B Neo groups.

End point values	RTS,S 14-26-9M Group	Engerix-B Neo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	46		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-measles	1017.7 (751.9 to 1377.4)	1430.6 (996.9 to 2053.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited local symptoms

End point title	Number of subjects reported with solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 0 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	58	60
Units: Subjects				
Any Pain	1	4	2	2
Any Redness	3	4	5	6
Any Swelling	2	4	5	6

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	59
Units: Subjects				
Any Pain	2	0	2	1
Any Redness	7	4	11	6
Any Swelling	5	5	8	6

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited local symptoms

End point title	Number of subjects reported with solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 6 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	55	54	57
Units: Subjects				
Any Pain	2	2	7	7
Any Redness	3	2	6	4
Any Swelling	4	3	6	8

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	55	58	51
Units: Subjects				
Any Pain	3	6	4	6
Any Redness	4	5	4	4

Any Swelling	6	6	6	6

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited local symptoms

End point title	Number of subjects reported with solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 10 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	54	51	54
Units: Subjects				
Any Pain	4	2	0	5
Any Redness	2	1	1	4
Any Swelling	4	1	3	6

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	52	57	51
Units: Subjects				
Any Pain	1	2	5	3
Any Redness	2	3	6	3
Any Swelling	3	3	6	3

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited local symptoms

End point title	Number of subjects reported with solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling. “Any” about a specific symptom is defined as incidence of this symptom, regardless of its intensity. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 14 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	53	51	54
Units: Subjects				
Any Pain	4	5	4	1
Any Redness	4	5	4	1
Any Swelling	7	5	4	1

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	50	57	52
Units: Subjects				
Any Pain	4	3	1	3
Any Redness	3	2	2	3
Any Swelling	4	4	2	3

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited local symptoms

End point title	Number of subjects reported with solicited local symptoms[20]

End point description:

Solicited local symptoms assessed include pain, redness and swelling. “Any” about a specific symptom is defined as incidence of this symptom, regardless of its intensity. RTS,S Neo-10-14 Group, RTS,S 6-10-14 Group and Engerix-B Neo Group did not receive vaccination at this time point. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 26 vaccination

Notes:

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

Justification: Groups considered were only those who received vaccination with either the BCG, HBV, measles, RTS,S/AS01E or the DTPwHepB/Hib vaccine(s) at Week 26.

End point values	RTS,S Neo-10-26 Group	RTS,S 6-10-26 Group	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	54	54	46
Units: Subjects				
Any Pain	0	0	0	0
Any Redness	0	0	0	0
Any Swelling	0	0	0	0

End point values	RTS,S 14-26-9M Group			
Subject group type	Reporting group			
Number of subjects analysed	56			
Units: Subjects				
Any Pain	0			
Any Redness	0			
Any Swelling	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited local symptoms

End point title	Number of subjects reported with solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling. “Any” about a specific symptom is defined as incidence of this symptom, regardless of its intensity. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Month 9 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	54
Units: Subjects				
Any Pain	0	0	0	0
Any Redness	0	0	0	0
Any Swelling	0	0	0	0

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	47	56	51
Units: Subjects				
Any Pain	0	0	0	0
Any Redness	0	0	0	0
Any Swelling	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited general symptoms

End point title	Number of subjects reported with solicited general symptoms

End point description:

Solicited general symptoms assessed include Drowsiness, Fever (temperature by axillary route ≥ 37.5°C), Irritability/Fussiness and Loss of appetite. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity or relationship to vaccination. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 0 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	58	60
Units: Subjects				
Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	0	1	0	1
Any Loss of appetite	0	0	0	0
Any Fever	8	9	6	3

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	59	60	59
Units: Subjects				
Any Drowsiness	0	1	0	1
Any Irritability/Fussiness	0	1	1	0
Any Loss of appetite	0	0	0	0
Any Fever	4	2	4	4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited general symptoms

End point title	Number of subjects reported with solicited general symptoms

End point description:

Solicited general symptoms assessed include Drowsiness, Fever (temperature by axillary route ≥ 37.5°C), Irritability/Fussiness and Loss of appetite. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity or relationship to vaccination. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 6 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	55	54	57
Units: Subjects				
Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	1	1	6	1
Any Loss of appetite	0	0	1	0
Any Fever	6	9	10	4

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	55	58	51
Units: Subjects				

Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	3	3	0	2
Any Loss of appetite	1	0	0	0
Any Fever	10	7	7	9

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited general symptoms

End point title	Number of subjects reported with solicited general symptoms

End point description:

Solicited general symptoms assessed include Drowsiness, Fever (temperature by axillary route ≥ 37.5°C), Irritability/Fussiness and Loss of appetite. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity or relationship to vaccination. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 10 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	54	51	54
Units: Subjects				
Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	3	2	0	1
Any Loss of appetite	0	0	0	0
Any Fever	11	7	6	6

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	51	57	51
Units: Subjects				
Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	0	1	0	1
Any Loss of appetite	0	0	0	0
Any Fever	4	7	2	2

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited general symptoms

End point title	Number of subjects reported with solicited general symptoms

End point description:

Solicited general symptoms assessed include Drowsiness, Fever (temperature by axillary route ≥ 37.5°C), Irritability/Fussiness and Loss of appetite. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity or relationship to vaccination. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 14 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	53	51	54
Units: Subjects				
Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	4	2	4	0
Any Loss of appetite	0	0	0	0
Any Fever	9	5	10	2

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	50	57	52
Units: Subjects				
Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	1	2	1	2
Any Loss of appetite	0	0	0	1
Any Fever	2	10	3	4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited general symptoms

End point title	Number of subjects reported with solicited general

End point description:

Solicited general symptoms assessed include Drowsiness, Fever (temperature by axillary route ≥ 37.5°C), Irritability/Fussiness and Loss of appetite. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity or relationship to vaccination. RTS,S Neo-10-14 Group, RTS,S 6-10-14 Group and Engerix-B Neo Group did not receive any vaccination at this time

that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Week 26 vaccination

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Groups considered were only those who received vaccination with either the BCG, HBV, measles, RTS,S/AS01E or the DTPwHepB/Hib vaccine(s) at Week 26.

End point values	RTS,S Neo-10-26 Group	RTS,S 6-10-26 Group	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	54	54	46
Units: Subjects				
Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	0	0	0	2
Any Loss of appetite	0	0	0	0
Any Fever	8	7	2	7

End point values	RTS,S 14-26-9M Group			
Subject group type	Reporting group			
Number of subjects analysed	56			
Units: Subjects				
Any Drowsiness	0			
Any Irritability/Fussiness	2			
Any Loss of appetite	1			
Any Fever	10			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reported with solicited general symptoms

End point title	Number of subjects reported with solicited general symptoms

End point description:

Solicited general symptoms assessed include Drowsiness, Fever (temperature by axillary route ≥ 37.5°C), Irritability/Fussiness and Loss of appetite. "Any" about a specific symptom is defined as incidence of this symptom, regardless of its intensity or relationship to vaccination. Please note that vaccines considered for the analyses of solicited local and general symptoms post vaccination were the BCG, HBV, measles, RTS,S/AS01E, and DTPwHepB/Hib vaccines only.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after Month 9 vaccination

End point values	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group	RTS,S 6-10-26 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	54
Units: Subjects				
Any Drowsiness	0	0	0	0
Any Irritability/Fussiness	0	2	0	0
Any Loss of appetite	0	1	0	0
Any Fever	1	5	6	2

End point values	Engerix-B Neo/RTS,S 6-10-26 Group	RTS,S 10-14-26 Group	RTS,S 14-26-9M Group	Engerix-B Neo Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	47	56	51
Units: Subjects				
Any Drowsiness	1	0	1	0
Any Irritability/Fussiness	2	0	2	0
Any Loss of appetite	1	0	1	0
Any Fever	3	2	10	1

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: 7 days post vaccination at Weeks 0, 6, 10, 14, 26 and Month 9 ; SAES: From Month 0 to Month 18 ; Unsolicited AEs: 30 days post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

Adverse event reporting additional description:

Note that 1) safety analysis for solicited symptoms and unsolicited AEs was performed only on subjects with available results; 2) 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	17.0

Reporting groups

Reporting group title	RTS,S Neo-10-14 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 14 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S Neo-10-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) when ≤ 7 days of age and at 10 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 6-10-14 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 14 weeks of age In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measlesvaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 6-10-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measlesvaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	Engerix-B Neo/RTS,S 6-10-26 Group

Reporting group description:

Subjects received one dose of EngerixTM-B (HBV) when ≤ 7 days of age followed by 3 doses of RTS,S/AS01E (GSK257049) at 6, 10 and 26 weeks of age In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E and HBV vaccines were administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 10-14-26 Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (GSK257049) at 10, 14 and 26 weeks of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	RTS,S 14-26-9M Group

Reporting group description:

Subjects received 3 doses of RTS,S/AS01E (or GSK257049) at 14 and 26 weeks of age and at 9 months of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when below ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when below ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The RTS,S/AS01E vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and Measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Reporting group title	Engerix-B Neo Group

Reporting group description:

Subjects in this group received one dose of EngerixTM-B (HBV) ≤ 7 days of age. In addition, all subjects received a 3-doses course of Tritanrix™HepB/Hib (DTPwHepB/Hib), administered at 6, 10 and 14 weeks of age, one dose of Bacille Calmette Guerin tuberculosis vaccine (BCG), administered when below ≤ 7 days of age, 4 doses of Polio Sabin™ (OPV), administered when ≤ 7 days of age and at 6, 10 and 14 weeks of age, and one dose of Rouvax™ (Measles), administered at 9 months of age. The HBV vaccine was administered intramuscularly (IM) in the left antero-lateral thigh. The DTPwHepB/Hib and measles vaccines were administered IM in the right antero-lateral thigh and the OPV vaccine orally. The BCG vaccine was administered via intradermal route in the shoulder.

Serious adverse events	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 60 (11.67%)	5 / 59 (8.47%)	6 / 60 (10.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Convulsion			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Drowning			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infections and infestations			
Abscess			

subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	2 / 60 (3.33%)	3 / 59 (5.08%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral malaria			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	1 / 60 (1.67%)	0 / 59 (0.00%)	0 / 60 (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
Escherichia sepsis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	4 / 60 (6.67%)	0 / 59 (0.00%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 60 (0.00%)	1 / 59 (1.69%)	0 / 60 (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
Malaria			

subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis neonatal			
subjects affected / exposed	1 / 60 (1.67%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 60 (3.33%)	1 / 59 (1.69%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Malnutrition			

subjects affected / exposed	0 / 60 (0.00%)	0 / 59 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	RTS,S 6-10-26 Group	Engerix-B Neo/RTS,S 6-10-26	RTS,S 10-14-26 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 60 (15.00%)	8 / 60 (13.33%)	12 / 60 (20.00%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	0 / 60 (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
Nervous system disorders			
Convulsion			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Drowning			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 60 (0.00%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory distress			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	0 / 60 (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
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	2 / 60 (3.33%)	2 / 60 (3.33%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 60 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral malaria			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Escherichia sepsis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 60 (3.33%)	4 / 60 (6.67%)	5 / 60 (8.33%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis neonatal			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	1 / 60 (1.67%)	1 / 60 (1.67%)	3 / 60 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 60 (0.00%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	RTS,S 14-26-9M Group	Engerix-B Neo Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 60 (8.33%)	4 / 60 (6.67%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			

subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal			
subjects affected / exposed	0 / 60 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Drowning			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 60 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			

subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral malaria			
subjects affected / exposed	0 / 60 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	2 / 60 (3.33%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaria			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis neonatal			

subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis pneumococcal			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 60 (3.33%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis neonatal			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	RTS,S Neo-10-14 Group	RTS,S Neo-10-26 Group	RTS,S 6-10-14 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 60 (60.00%)	35 / 59 (59.32%)	28 / 60 (46.67%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	4 / 60 (6.67%)	5 / 59 (8.47%)	7 / 58 (12.07%)
occurrences (all)	4	5	7
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	4 / 60 (6.67%)	5 / 59 (8.47%)	6 / 58 (10.34%)
occurrences (all)	4	5	6
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	7 / 60 (11.67%)	5 / 59 (8.47%)	6 / 58 (10.34%)
occurrences (all)	7	5	6
Irritability			
subjects affected / exposed[4]	4 / 60 (6.67%)	2 / 59 (3.39%)	6 / 58 (10.34%)
occurrences (all)	4	2	6
Fever (axillary temperature >= 37.5°C)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	11 / 60 (18.33%)	9 / 59 (15.25%)	10 / 58 (17.24%)
occurrences (all)	11	9	10
Pyrexia			
subjects affected / exposed[6]	3 / 60 (5.00%)	2 / 59 (3.39%)	5 / 54 (9.26%)
occurrences (all)	3	2	5
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed[7]	1 / 60 (1.67%)	2 / 59 (3.39%)	3 / 54 (5.56%)
occurrences (all)	1	2	3
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed[8]	2 / 60 (3.33%)	2 / 59 (3.39%)	3 / 54 (5.56%)
occurrences (all)	2	2	3
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed[9]	4 / 60 (6.67%)	2 / 59 (3.39%)	0 / 54 (0.00%)
occurrences (all)	4	2	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed[10]	0 / 60 (0.00%)	0 / 59 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed[11]	4 / 60 (6.67%)	5 / 59 (8.47%)	1 / 54 (1.85%)
occurrences (all)	4	5	1
Gastroenteritis			
subjects affected / exposed[12]	3 / 60 (5.00%)	5 / 59 (8.47%)	0 / 54 (0.00%)
occurrences (all)	3	5	0
Malaria			
subjects affected / exposed[13]	5 / 60 (8.33%)	3 / 59 (5.08%)	2 / 54 (3.70%)
occurrences (all)	5	3	2
Nasopharyngitis			
subjects affected / exposed[14]	6 / 60 (10.00%)	3 / 59 (5.08%)	6 / 54 (11.11%)
occurrences (all)	6	3	6
Oral candidiasis			
subjects affected / exposed[15]	1 / 60 (1.67%)	3 / 59 (5.08%)	0 / 54 (0.00%)
occurrences (all)	1	3	0
Pneumonia			
subjects affected / exposed[16]	8 / 60 (13.33%)	6 / 59 (10.17%)	3 / 54 (5.56%)
occurrences (all)	8	6	3
Respiratory tract infection			
subjects affected / exposed[17]	1 / 60 (1.67%)	2 / 59 (3.39%)	0 / 54 (0.00%)
occurrences (all)	1	2	0
Upper respiratory tract infection			
subjects affected / exposed[18]	11 / 60 (18.33%)	15 / 59 (25.42%)	10 / 54 (18.52%)
occurrences (all)	11	15	10

Non-serious adverse events	RTS,S 6-10-26	Engerix-B Neo/RTS,	RTS,S 10-14-26

	Group	S 6-10-26 Group	Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 60 (48.33%)	35 / 60 (58.33%)	36 / 60 (60.00%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	7 / 60 (11.67%)	4 / 60 (6.67%)	6 / 59 (10.17%)
occurrences (all)	7	4	6
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	6 / 60 (10.00%)	7 / 60 (11.67%)	5 / 59 (8.47%)
occurrences (all)	6	7	5
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	8 / 60 (13.33%)	6 / 60 (10.00%)	6 / 59 (10.17%)
occurrences (all)	8	6	6
Irritability			
subjects affected / exposed[4]	1 / 60 (1.67%)	3 / 60 (5.00%)	3 / 59 (5.08%)
occurrences (all)	1	3	3
Fever (axillary temperature >= 37.5°C)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	7 / 60 (11.67%)	10 / 60 (16.67%)	10 / 59 (16.95%)
occurrences (all)	7	10	10
Pyrexia			
subjects affected / exposed[6]	1 / 57 (1.75%)	5 / 57 (8.77%)	2 / 52 (3.85%)
occurrences (all)	1	5	2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed[7]	2 / 57 (3.51%)	3 / 57 (5.26%)	1 / 52 (1.92%)
occurrences (all)	2	3	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed[8]	0 / 57 (0.00%)	5 / 57 (8.77%)	2 / 52 (3.85%)
occurrences (all)	0	5	2
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed[9]	2 / 57 (3.51%)	3 / 57 (5.26%)	5 / 52 (9.62%)
occurrences (all)	2	3	5
Infections and infestations			
Bronchiolitis			
subjects affected / exposed[10]	3 / 57 (5.26%)	2 / 57 (3.51%)	0 / 52 (0.00%)
occurrences (all)	3	2	0
Conjunctivitis			
subjects affected / exposed[11]	2 / 57 (3.51%)	2 / 57 (3.51%)	6 / 52 (11.54%)
occurrences (all)	2	2	6
Gastroenteritis			
subjects affected / exposed[12]	3 / 57 (5.26%)	2 / 57 (3.51%)	9 / 52 (17.31%)
occurrences (all)	3	2	9
Malaria			
subjects affected / exposed[13]	0 / 57 (0.00%)	4 / 57 (7.02%)	5 / 52 (9.62%)
occurrences (all)	0	4	5
Nasopharyngitis			
subjects affected / exposed[14]	6 / 57 (10.53%)	3 / 57 (5.26%)	3 / 52 (5.77%)
occurrences (all)	6	3	3
Oral candidiasis			
subjects affected / exposed[15]	0 / 57 (0.00%)	1 / 57 (1.75%)	1 / 52 (1.92%)
occurrences (all)	0	1	1
Pneumonia			
subjects affected / exposed[16]	7 / 57 (12.28%)	6 / 57 (10.53%)	5 / 52 (9.62%)
occurrences (all)	7	6	5
Respiratory tract infection			
subjects affected / exposed[17]	3 / 57 (5.26%)	1 / 57 (1.75%)	0 / 52 (0.00%)
occurrences (all)	3	1	0
Upper respiratory tract infection			
subjects affected / exposed[18]	6 / 57 (10.53%)	11 / 57 (19.30%)	13 / 52 (25.00%)
occurrences (all)	6	11	13

Non-serious adverse events	RTS,S 14-26-9M Group	Engerix-B Neo Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 60 (78.33%)	31 / 60 (51.67%)	
General disorders and administration site conditions			

Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	5 / 60 (8.33%)	6 / 59 (10.17%)	
occurrences (all)	5	6	
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	11 / 60 (18.33%)	6 / 59 (10.17%)	
occurrences (all)	11	6	
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	8 / 60 (13.33%)	6 / 59 (10.17%)	
occurrences (all)	8	6	
Irritability			
subjects affected / exposed[4]	2 / 60 (3.33%)	2 / 59 (3.39%)	
occurrences (all)	2	2	
Fever (axillary temperature >= 37.5°C)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	10 / 60 (16.67%)	9 / 59 (15.25%)	
occurrences (all)	10	9	
Pyrexia			
subjects affected / exposed[6]	3 / 57 (5.26%)	1 / 52 (1.92%)	
occurrences (all)	3	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed[7]	2 / 57 (3.51%)	2 / 52 (3.85%)	
occurrences (all)	2	2	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed[8]	4 / 57 (7.02%)	3 / 52 (5.77%)	
occurrences (all)	4	3	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed[9]	2 / 57 (3.51%)	2 / 52 (3.85%)	
occurrences (all)	2	2	
Infections and infestations			

Bronchiolitis			
subjects affected / exposed[10]	0 / 57 (0.00%)	0 / 52 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed[11]	5 / 57 (8.77%)	2 / 52 (3.85%)	
occurrences (all)	5	2	
Gastroenteritis			
subjects affected / exposed[12]	8 / 57 (14.04%)	2 / 52 (3.85%)	
occurrences (all)	8	2	
Malaria			
subjects affected / exposed[13]	9 / 57 (15.79%)	0 / 52 (0.00%)	
occurrences (all)	9	0	
Nasopharyngitis			
subjects affected / exposed[14]	7 / 57 (12.28%)	7 / 52 (13.46%)	
occurrences (all)	7	7	
Oral candidiasis			
subjects affected / exposed[15]	1 / 57 (1.75%)	0 / 52 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed[16]	9 / 57 (15.79%)	6 / 52 (11.54%)	
occurrences (all)	9	6	
Respiratory tract infection			
subjects affected / exposed[17]	1 / 57 (1.75%)	0 / 52 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed[18]	15 / 57 (26.32%)	13 / 52 (25.00%)	
occurrences (all)	15	13	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited symptoms results were only collected in subjects having results available for the 7-day (Days 0-6) periods post vaccination with the BCG, HBV, measles, RTS,S/AS01E or the DTPwHepB/Hib vaccine(s) at Week 26. at Weeks 0, 6, 10, 14, 26 and/or Month 9.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited symptoms results were only collected in subjects having results available for the 7-day (Days 0-6) periods post vaccination with the BCG, HBV, measles, RTS,S/AS01E or the DTPwHepB/Hib vaccine(s) at Week 26. at Weeks 0, 6, 10, 14, 26 and/or Month 9.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: Solicited symptoms results were only collected in subjects having results available for the 7-day (Days 0-6) periods post vaccination with the BCG, HBV, measles, RTS,S/AS01E or the DTPwHepB/Hib vaccine(s) at Week 26. at Weeks 0, 6, 10, 14, 26 and/or Month 9.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited symptoms results were only collected in subjects having results available for the 7-day (Days 0-6) periods post vaccination with the BCG, HBV, measles, RTS,S/AS01E or the DTPwHepB/Hib vaccine(s) at Week 26. at Weeks 0, 6, 10, 14, 26 and/or Month 9.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited symptoms results were only collected in subjects having results available for the 7-day (Days 0-6) periods post vaccination with the BCG, HBV, measles, RTS,S/AS01E or the DTPwHepB/Hib vaccine(s) at Week 26. at Weeks 0, 6, 10, 14, 26 and/or Month 9.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[14] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Unsolicited AEs results were only collected in subjects having results available for the 30-day (Days 0-29) period post vaccination with 3 doses of RTS,S/AS01E versus DTPwHepB/Hib for the Engerix-B Neo Group.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 November 2008	The study design was modified for the inclusion of an additional study group with a 14, 26-week and 9 month RTS,S/AS01E schedule. This schedule explores a possible schedule outside the EPI DTPw-HepB/Hib vaccination schedule, but still co-administers 2 of the doses at existing EPI visits. A number of changes were made to the protocol as a consequence. The administration of a measles vaccine (Rouvax) was described. The study was revised from including three sites to one study site.
02 April 2009	GSK no longer makes the Zilbrix Hib DTPwHepB/Hib vaccine. This study therefore used a similar DTPHepB/Hib vaccine manufactured by GSK, Tritanrix HepB/Hib. The primary difference is that Zilbrix Hib a lower quantity of PRP antigen per dose than Tritanrix HepB/Hib (5 fold difference).
20 April 2010	Exclusion and elimination criteria on investigational or non-registered product were reworded. The blood volume specified for the collection of hematology and biochemistry safety bloods was increased to provide sufficient sample volume for analysis. In order to be able to obtain cord blood and where possible, to allow parent(s)/guardian(s) (LARs) extra time to understand the information provided to them BEFORE the child birth, an ICF was developed to provide the full information. Since this information sheet and consent could have been provided up to 3 months prior to the child birth, it was felt necessary to obtain confirmation of continued consent PRIOR to any study procedure being carried out on the infant. Using this process it was also possible for parent(s)/LARs to consent to take part in the study up to 7 days after birth if they were unable to provide consent prior to birth. The informed consent procedure was modified to avoid having to obtain consent at a sensitive time (around the birth). Based on concern that the use of new adjuvanted vaccines could promote a rupture of immunological self-tolerance, regulatory authorities required the optimization of data collection on auto-immune diseases. As a result, it was decided to define pIMDs as an adverse event of interest and to optimize auto-immunity data collection processes in studies of adjuvanted candidate vaccines, with reporting of these events being added for the entire study period. A pooled analysis of safety data performed on all controlled Phase II pediatric RTS,S/AS vaccine trials revealed an imbalance in the reporting of rashes and diaper rashes as AEs occurring in infants less than 5 months of age. As a result, the safety reporting included adverse events of specific interest, namely rashes and mucocutaneous lesions. Rashes and mucocutaneous lesions that occurred within 30 days of vaccination were to be documented and analyzed according to the Brighton Collaboration Guidelines.
28 June 2011	The rationale for this amendment was to ensure better safety assessment of enrolled subjects, enhance community confidence and acceptability of the study and also improve subject enrolment by: 1) Allowing for repeat safety blood samples to be drawn at any of the follow-up safety assessment time points in the event that the initial safety blood sample drawn was unsuitable for analysis; 2) Removal of the enrolment pause during Safety Report 4 (i.e. when 60 neonates have received neonatal RTS,S/AS01E doses). 3) Allowing for a repeat blood sample to be taken from a neonate at enrolment for: a) safety re-screening in the event that the initial screening blood sample failed the eligibility criteria, b) safety screening in the event that the initial screening blood sample was unsuitable for analysis, c) re-screening for both safety and immunogenicity in the event that the 24 hour maximum interval between blood sampling and enrolment is exceeded; 4) Extending the study from a single-center to a multi-center study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported