Clinical trial results:
A Phase III, open, multicentre study to assess the long-term persistence of a booster dose of GlaxoSmithKline (GSK) Biologicals' Haemophilus influenzae type b-meningococcal serogroup C conjugate vaccine (Hib-MenC) compared to a booster dose of Infanrix™ hexa (combined diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio-Hib vaccine) when given to 14-month-old subjects who were primed in study 217744/097 (DTPa-HBV-IPV-097) and boosted in study Hib-MenC-TT-010 BST: DTPa-HBV-IPV-097

Summary

EudraCT number	2006-000518-19
Trial protocol	ES
Global end of trial date	08 September 2010

Results information

Result version number	v2 (current)
This version publication date	13 August 2016
First version publication date	22 May 2015
Version creation reason	• Correction of full data set Data (typos) were corrected in section endpoints.

Trial information

Trial identification

Sponsor protocol code	106672;106673;106675;106679;-80

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00322335
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 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	Yes

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 May 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 September 2010
Global end of trial reached?	Yes
Global end of trial date	08 September 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the persistence of Meningococcal C antibodies on a yearly basis for a period of 5.5 years after booster vaccination.
To evaluate the persistence of Haemophilus influenzae type b antibodies on a yearly basis for a period of 5.5 years after booster vaccination

Protection of trial subjects:

All subjects were supervised for 30 min after vaccination administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel only to eligible subjects that had no contraindications to any components of the vaccines. Subjects were followed-up from the day of vaccination and the subsequent 30 days after the last vaccination administration.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 May 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	4 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 184
Worldwide total number of subjects	184
EEA total number of subjects	184

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	184
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:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Pre-assignment period milestones

Number of subjects started	184
Number of subjects completed	184

Period 1

Period 1 title	Month 18
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Menitorix/Pediarix Group Month 18

Arm description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Experimental
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ penta
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Arm title	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18

Arm description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with

Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Engerix-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as a birth dose

Investigational medicinal product name	NeisVac-C™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2 and 4 months of age.

Investigational medicinal product name	Infanrix™ IPV/HIB
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 4 months of age.

Arm title	Infanrix hexa/Meningitec Group Month 18

Arm description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator
Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Number of subjects in period 1	Menitorix/Pediarix Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Meningitec Group Month 18
Started	58	123	3
Completed	58	123	3

Period 2

Period 2 title	Month 30
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Menitorix/Pediarix Group Month 30

Arm description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Experimental
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ penta
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection

Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Arm title	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30

Arm description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Engerix-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as a birth dose

Investigational medicinal product name	NeisVac-C™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2 and 4 months of age.

Investigational medicinal product name	Infanrix™ IPV/HIB
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 4 months of age

Arm title	Infanrix hexa/Meningitec Group Month 30

Arm description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator
Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Number of subjects in period 2[1]	Menitorix/Pediarix Group Month 30	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Meningitec Group Month 30
Started	54	119	3
Completed	54	119	57
Joined	0	0	54
Late return to study visit	-	-	54

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all subjects completing one period came to the next study visit; however, a subject missing a previous visit was allowed to return to a subsequent one. Thus, the number of subjects starting every study period is based on the actual rate of return.

Period 3

Period 3 title	Month 42
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	Menitorix/Pediarix Group Month 42

Arm description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Experimental
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ penta
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Arm title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42

Arm description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Engerix-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details: Intramuscular injection into the thigh as a birth dose	
Investigational medicinal product name	NeisVac-C™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection into the thigh as primary vaccination at 2 and 4 months of age.	
Investigational medicinal product name	Infanrix™ IPV/HIB
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection into the thigh as primary vaccination at 4 months of age.	
Arm title	Infanrix hexa/Meningitec Group Month 42
Arm description: Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.	
Arm type	Active comparator
Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).	
Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age	

Number of subjects in period 3[2]	Menitorix/Pediarix Group Month 42	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42	Infanrix hexa/Meningitec Group Month 42
Started	51	113	56
Completed	51	113	56

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all subjects completing one period came to the next study visit; however, a subject missing a previous visit was allowed to return to a subsequent one. Thus, the number of subjects starting every study period is based on the actual rate of return.

Period 4

Period 4 title	Month 54
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Menitorix/Pediarix Group Month 54

Arm description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Experimental
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ penta
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Arm title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54

Arm description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group

HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Engerix-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as a birth dose

Investigational medicinal product name	NeisVac-C™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2 and 4 months of age.

Investigational medicinal product name	Infanrix™ IPV/HIB
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 4 months of age.

Arm title	Infanrix hexa/Meningitec Group Month 54

Arm description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator
Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Number of subjects in period 4[3]	Menitorix/Pediarix Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Meningitec Group Month 54
Started	50	108	56
Completed	50	108	56

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all subjects completing one period came to the next study visit; however, a subject missing a previous visit was allowed to return to a subsequent one. Thus, the number of subjects starting every study period is based on the actual rate of return.

Period 5

Period 5 title	Month 66
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Menitorix/Pediarix Group Month 66

Arm description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Experimental
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ penta
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Arm title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66

Arm description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of

age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator
Investigational medicinal product name	Menitorix™
Investigational medicinal product code	
Other name	Haemophilus influenzae type b- and meningococcal (vaccine)
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age (group HibMenC) and as booster dose at 14 months of age (groups HibMenC and group NeisPoo).

Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Engerix-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as a birth dose

Investigational medicinal product name	NeisVac-C™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2 and 4 months of age.

Investigational medicinal product name	Infanrix™ IPV/HIB
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 4 months of age.

Arm title	Infanrix hexa/Meningitec Group Month 66

Arm description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Arm type	Active comparator

Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and/or 6 months of age (groups NeisPoo and MenCCRM) and/or as booster dose at 14 months of age (group MenCCRM).

Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection into the thigh as primary vaccination at 2, 4 and 6 months of age

Number of subjects in period 5[4]	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 66
Started	48	104	53
Completed	48	104	53

Notes:

[4] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all subjects completing one period came to the next study visit; however, a subject missing a previous visit was allowed to return to a subsequent one. Thus, the number of subjects starting every study period is based on the actual rate of return.

Baseline characteristics

Reporting groups	
Reporting group title	Menitorix/Pediarix Group Month 18

Reporting group description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18

Reporting group description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Meningitec Group Month 18

Reporting group description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Reporting group values	Menitorix/Pediarix Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Meningitec Group Month 18
Number of subjects	58	123	3
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: months			
arithmetic mean	31.3	31.4	31.3
standard deviation	± 0.54	± 0.64	± 0.58
Gender categorical Units: Subjects			
Female	27	55	1
Male	31	68	2

Reporting group values	Total		
Number of subjects	184		
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: months			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	83		
Male	101		

Subject analysis sets

Subject analysis set title	Pooled Group Month 18
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 18 (Menitorix/Pediarix Group Month 18 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18).

Subject analysis set title	Pooled Group Month 30
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 30 (Menitorix/Pediarix Group Month 30 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30).

Subject analysis set title	Pooled Group Month 42
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 42 (Menitorix/Pediarix Group Month 42 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 42).

Subject analysis set title	Pooled Group Month 54
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 54 (Menitorix/Pediarix Group Month 54 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 54).

Subject analysis set title	Pooled Group Month 66
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary

Reporting group values	Pooled Group Month 18	Pooled Group Month 30	Pooled Group Month 42
Number of subjects	181	173	164
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: months			
arithmetic mean	31.3	43.3	55.6
standard deviation	± 0.61	± 0.78	± 0.82
Gender categorical			
Units: Subjects			
Female	82	77	74
Male	99	96	90

Reporting group values	Pooled Group Month 54	Pooled Group Month 66	
Number of subjects	158	152	
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: months			
arithmetic mean	67.4	79.2	
standard deviation	± 0.6	± 0.82	
Gender categorical			
Units: Subjects			
Female	70	66	
Male	88	86	

End points

End points reporting groups

Reporting group title	Menitorix/Pediarix Group Month 18

Reporting group description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18

Reporting group description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Meningitec Group Month 18

Reporting group description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Menitorix/Pediarix Group Month 30

Reporting group description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30

Reporting group description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Meningitec Group Month 30

Reporting group description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Menitorix/Pediarix Group Month 42

Reporting group description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42

Reporting group description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Meningitec Group Month 42

Reporting group description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Menitorix/Pediarix Group Month 54

Reporting group description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54

Reporting group description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Meningitec Group Month 54

Reporting group description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Menitorix/Pediarix Group Month 66

Reporting group description:

Subjects were primed with 3 doses of Pediarix™ co-administered intramuscularly with Menitorix™ in the right and left thigh respectively in the primary study (NCT00352963) at 2, 4 and 6 months of age. This was followed by a booster dose of Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66

Reporting group description:

Subjects were either primed in the primary study (NCT00352963) with 3 doses of Infanrix™ hexa administered intramuscularly in the right thigh at 2, 4 and 6 months of age and 2 doses of NeisVac-C™ administered intramuscularly in the left thigh at 2 and 4 months of age or with Engerix-B at birth intramuscularly in the right thigh, Infanrix™ hexa intramusculary in the right thigh at 2 and 6 months of age and NeisVac-C™ intramuscularly in the left thigh at 2 and 4 months of age, Infanrix™ IPV/Hib was administered intramuscularly in the right thigh at 4 months of age. All subjects were boosted with Menitorix™ administered intramuscularly in the left thigh between 13 and 14 months of age in study NCT00323050. No vaccines were administered during this long-term persistence phase of the study.

Reporting group title	Infanrix hexa/Meningitec Group Month 66

Reporting group description:

Subjects were primed with Infanrix™ hexa co-administered intramuscularly with Meningitec™ in the right and left thigh respectively at 2, 4 and 6 months of age during the primary study (NCT00352963), followed by a booster dose of Infanrix™ hexa intramuscularly in the right thigh between 13 and 14 months of age in study (NCT00323050). No vaccines were administered during this long-term

persistence phase of the study.

Subject analysis set title	Pooled Group Month 18
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 18 (Menitorix/Pediarix Group Month 18 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18).

Subject analysis set title	Pooled Group Month 30
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 30 (Menitorix/Pediarix Group Month 30 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30).

Subject analysis set title	Pooled Group Month 42
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 42 (Menitorix/Pediarix Group Month 42 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 42).

Subject analysis set title	Pooled Group Month 54
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 54 (Menitorix/Pediarix Group Month 54 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 54).

Subject analysis set title	Pooled Group Month 66
Subject analysis set type	Sub-group analysis

Subject analysis set description:

To analyse the post-booster data, subjects boosted with Menitorix™ were pooled across primary vaccination schedules into Pooled Group Month 66 (Menitorix/Pediarix Group Month 66 and Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 66).

Primary: Number of subjects with meningococcal serogroup C serum bactericidal assay using rabbit complement (rSBA-MenC) titers equal to or above cut-off value of 1:8

End point title	Number of subjects with meningococcal serogroup C serum bactericidal assay using rabbit complement (rSBA-MenC) titers equal to or above cut-off value of 1:8[1][2]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after booster dose (Day 0)

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.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on groups with more than 0 subjects with available blood samples for the respective timepoint.

End point values	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	48	50	49
Units: Subjects				
rSBA-MenC ≥ 1:8	44	39	39	38

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	96	101	110
Units: Subjects				
rSBA-MenC ≥ 1:8	38	93	96	106

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 30	Infanrix hexa/Meningitec Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	101	45	52
Units: Subjects				
rSBA-MenC ≥ 1:8	103	95	31	33

End point values	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18	Pooled Group Month 30
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	51	46	141	149
Units: Subjects				
rSBA-MenC ≥ 1:8	33	28	137	135

End point values	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	160	155	147	
Units: Subjects				
rSBA-MenC ≥ 1:8	145	141	133	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with meningococcal serogroup C serum bactericidal assay using rabbit complement (rSBA-MenC) titers equal to or above cut-off value of 1:32

End point title	Number of subjects with meningococcal serogroup C serum bactericidal assay using rabbit complement (rSBA-MenC) titers equal to or above cut-off value of 1:32[3][4]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after booster dose (Day 0)

Notes:

[3] - 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.
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on groups with more than 0 subjects with available blood samples for the respective timepoint.

End point values	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	48	50	49
Units: Subjects				
rSBA-MenC ≥ 1:32	40	36	38	37

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	96	101	110
Units: Subjects				
rSBA-MenC ≥ 1:32	37	93	94	100

End point values	Infanrix hexa/Infanrix	Infanrix hexa/Infanrix	Infanrix hexa/Meningite	Infanrix hexa/Meningite

	IPV/Hib co-ad Group Month 54	IPV/Hib co-ad Group Month 66	c Group Month 30	c Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	101	45	52
Units: Subjects				
rSBA-MenC ≥ 1:32	100	88	25	30

End point values	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18	Pooled Group Month 30
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	51	46	141	149
Units: Subjects				
rSBA-MenC ≥ 1:32	29	25	133	130

End point values	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	160	155	147	
Units: Subjects				
rSBA-MenC ≥ 1:32	138	137	125	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with meningococcal serogroup C serum bactericidal assay using rabbit complement (rSBA-MenC) titers equal to or above cut-off value of 1:128

End point title	Number of subjects with meningococcal serogroup C serum bactericidal assay using rabbit complement (rSBA-MenC) titers equal to or above cut-off value of 1:128[5][6]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after booster dose (Day 0)

Notes:

[5] - 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.
[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on groups with more than 0 subjects with available blood samples for the respective timepoint.

End point values	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	48	50	49
Units: Subjects				
rSBA-MenC ≥ 1:128	27	27	30	27

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	96	101	110
Units: Subjects				
rSBA-MenC ≥ 1:128	28	82	80	89

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 30	Infanrix hexa/Meningitec Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	101	45	52
Units: Subjects				
rSBA-MenC ≥ 1:128	86	69	12	13

End point values	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18	Pooled Group Month 30
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	51	46	141	149
Units: Subjects				
rSBA-MenC ≥ 1:128	15	18	109	107

End point values	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	160	155	147	
Units: Subjects				
rSBA-MenC ≥ 1:128	119	113	97	

Statistical analyses

No statistical analyses for this end point

Primary: rSBA-MenC titers

End point title	rSBA-MenC titers[7][8]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after booster dose (Day 0)

Notes:

[7] - 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.
[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on groups with more than 0 subjects with available blood samples for the respective timepoint.

End point values	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	48	50	49
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenC	221.5 (137.2 to 357.7)	109.1 (61.9 to 192.3)	98.9 (56.7 to 172.5)	90.4 (52.8 to 154.8)

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	96	101	110
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenC	121.5 (71 to 207.9)	801.1 (570.3 to 1125.3)	441.7 (309.4 to 630.6)	409.8 (297.7 to 564.2)

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 30	Infanrix hexa/Meningitec Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	101	45	52
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenC	344.6 (255.9 to 463.9)	227.6 (160.2 to 323.3)	40.3 (21.9 to 74.1)	36.1 (20.4 to 63.8)

End point values	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18	Pooled Group Month 30
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	51	46	141	149
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenC	36.7 (21.1 to 64)	42.7 (22.3 to 81.8)	531.5 (397.1 to 711.6)	281.5 (205 to 386.6)

End point values	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	160	155	147	
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenC	262.8 (195.6 to 353.2)	225.7 (170.6 to 298.6)	187 (139.3 to 251)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with anti-polyribosylribitol phosphate (Anti-PRP) concentrations equal to or above cut-off value of 0.15 µg/mL

End point title	Number of subjects with anti-polyribosylribitol phosphate (Anti-PRP) concentrations equal to or above cut-off value of 0.15 µg/mL[9]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after the booster dose (Day 0)

Notes:

[9] - 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	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	53	50	49
Units: Subjects				
Anti-PRP ≥ 0.15	56	53	50	49

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	122	113	110
Units: Subjects				
Anti-PRP ≥ 0.15	47	121	112	109

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 18	Infanrix hexa/Meningitec Group Month 30
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	101	3	53
Units: Subjects				
Anti-PRP ≥ 0.15	105	101	3	53

End point values	Infanrix hexa/Meningitec Group Month 42	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	52	47	178
Units: Subjects				
Anti-PRP ≥ 0.15	51	52	46	177

End point values	Pooled Group Month 30	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	166	160	155	148
Units: Subjects				
Anti-PRP ≥ 0.15	165	159	154	148

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with anti-polyribosylribitol phosphate (Anti-PRP) concentrations equal to or above cut-off value of 1.0 µg/mL

End point title	Number of subjects with anti-polyribosylribitol phosphate (Anti-PRP) concentrations equal to or above cut-off value of 1.0 µg/mL[10]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after the booster dose (Day 0)

Notes:

[10] - 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	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	53	50	49
Units: Subjects				
Anti-PRP ≥ 1.0	44	36	33	27

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	122	113	110
Units: Subjects				
Anti-PRP ≥ 1.0	26	112	98	91

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 18	Infanrix hexa/Meningitec Group Month 30

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	101	3	53
Units: Subjects				
Anti-PRP ≥ 1.0	86	84	3	40

End point values	Infanrix hexa/Meningitec Group Month 42	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	52	47	178
Units: Subjects				
Anti-PRP ≥ 1.0	34	35	26	156

End point values	Pooled Group Month 30	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	166	160	155	148
Units: Subjects				
Anti-PRP ≥ 1.0	134	124	113	110

Statistical analyses

No statistical analyses for this end point

Primary: Anti-PRP concentrations

End point title	Anti-PRP concentrations[11]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after the booster dose (Day 0)

Notes:

[11] - 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	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	53	50	49
Units: µg/mL				
geometric mean (confidence interval 95%)				

Anti-PRP	2.921 (2.15 to 3.968)	1.914 (1.383 to 2.648)	1.735 (1.243 to 2.423)	1.552 (1.154 to 2.087)

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	122	113	110
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP	1.602 (1.107 to 2.32)	5.45 (4.39 to 6.766)	3.524 (2.813 to 4.415)	2.986 (2.395 to 3.722)

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 18	Infanrix hexa/Meningitec Group Month 30
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	101	3	53
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP	2.688 (2.149 to 3.361)	2.625 (2.113 to 3.261)	2.547 (0.39 to 16.651)	2.224 (1.578 to 3.133)

End point values	Infanrix hexa/Meningitec Group Month 42	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	52	47	178
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP	2.005 (1.365 to 2.946)	1.799 (1.267 to 2.555)	1.763 (1.17 to 2.657)	4.479 (3.74 to 5.364)

End point values	Pooled Group Month 30	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	166	160	155	148
Units: µg/mL				
geometric mean (confidence interval				

95%)				
Anti-PRP	2.9 (2.402 to 3.501)	2.52 (2.092 to 3.036)	2.259 (1.883 to 2.71)	2.244 (1.855 to 2.714)

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with anti-polysaccharide C (Anti-PSC) concentrations equal to or above cut-off value of 0.3 µg/mL

End point title	Number of subjects with anti-polysaccharide C (Anti-PSC) concentrations equal to or above cut-off value of 0.3 µg/mL[12][13]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after the booster dose (Day 0)

Notes:

[12] - 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.
[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on groups with more than 0 subjects with available blood samples for the respective timepoint.

End point values	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	52	49	46
Units: Subjects				
Anti-PSC ≥ 0.3	38	19	17	14

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	122	108	107
Units: Subjects				
Anti-PSC ≥ 0.3	12	100	58	52

End point values	Infanrix hexa/Infanrix	Infanrix hexa/Infanrix	Infanrix hexa/Meningite	Infanrix hexa/Meningite

	IPV/Hib co-ad Group Month 54	IPV/Hib co-ad Group Month 66	c Group Month 30	c Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	105	99	53	52
Units: Subjects				
Anti-PSC ≥ 0.3	52	34	19	17

End point values	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18	Pooled Group Month 30
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	52	45	178	160
Units: Subjects				
Anti-PSC ≥ 0.3	17	11	138	77

End point values	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	156	151	144	
Units: Subjects				
Anti-PSC ≥ 0.3	69	66	46	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with anti-polysaccharide C (Anti-PSC) concentrations equal to or above cut-off value of 2.0 µg/mL

End point title	Number of subjects with anti-polysaccharide C (Anti-PSC) concentrations equal to or above cut-off value of 2.0 µg/mL[14][15]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after the booster dose (Day 0)

Notes:

[14] - 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.
[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on groups with more than 0 subjects with available blood

samples for the respective timepoint.

End point values	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	52	49	46
Units: Subjects				
Anti-PSC ≥ 2.0	1	1	0	1

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	122	108	107
Units: Subjects				
Anti-PSC ≥ 2.0	0	31	18	14

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 30	Infanrix hexa/Meningitec Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	105	99	53	52
Units: Subjects				
Anti-PSC ≥ 2.0	10	8	3	2

End point values	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18	Pooled Group Month 30
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	52	45	178	160
Units: Subjects				
Anti-PSC ≥ 2.0	1	0	32	19

End point values	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	156	151	144	
Units: Subjects				

Anti-PSC ≥ 2.0	14	11	8	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events

End point title	Number of subjects with serious adverse events[16]

End point description:

End point type	Primary

End point timeframe:

From last study contact of the booster study (NCT00323050) to Month 66 after booster dose (Day 0)

Notes:

[16] - 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	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	54	51	50
Units: Subjects				
Any SAEs	0	0	0	0

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	123	119	113
Units: Subjects				
Any SAEs	0	0	0	0

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 18	Infanrix hexa/Meningitec Group Month 30
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	108	104	3	57
Units: Subjects				
Any SAEs	0	0	0	0

End point values	Infanrix hexa/Meningitec Group Month 42	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	56	56	53	181
Units: Subjects				
Any SAEs	0	0	0	0

End point values	Pooled Group Month 30	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	173	164	158	152
Units: Subjects				
Any SAEs	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Anti-PSC concentrations

End point title	Anti-PSC concentrations[17][18]

End point description:

End point type	Primary

End point timeframe:

18, 30, 42, 54 and 66 months after the booster dose (Day 0)

Notes:

[17] - 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.
[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on groups with more than 0 subjects with available blood samples for the respective timepoint.

End point values	Menitorix/Pediarix Group Month 18	Menitorix/Pediarix Group Month 30	Menitorix/Pediarix Group Month 42	Menitorix/Pediarix Group Month 54
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	52	49	46
Units: µg/mL				
geometric mean (confidence interval 95%)				

Anti-PSC	0.5 (0.39 to 0.64)	0.26 (0.21 to 0.33)	0.25 (0.2 to 0.31)	0.24 (0.19 to 0.3)

End point values	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	122	108	107
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSC	0.22 (0.18 to 0.27)	1.01 (0.8 to 1.29)	0.47 (0.37 to 0.61)	0.4 (0.32 to 0.51)

End point values	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 30	Infanrix hexa/Meningitec Group Month 42
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	105	99	53	52
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSC	0.36 (0.29 to 0.45)	0.29 (0.23 to 0.36)	0.3 (0.23 to 0.39)	0.28 (0.21 to 0.37)

End point values	Infanrix hexa/Meningitec Group Month 54	Infanrix hexa/Meningitec Group Month 66	Pooled Group Month 18	Pooled Group Month 30
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	52	45	178	160
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSC	0.26 (0.2 to 0.32)	0.22 (0.18 to 0.28)	0.81 (0.67 to 0.98)	0.39 (0.32 to 0.47)

End point values	Pooled Group Month 42	Pooled Group Month 54	Pooled Group Month 66	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	156	151	144	
Units: µg/mL				
geometric mean (confidence interval				

95%)				
Anti-PSC	0.35 (0.29 to 0.42)	0.32 (0.27 to 0.38)	0.26 (0.22 to 0.31)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: From last study contact of the booster study (NCT00323050) to Month 66 after booster dose (Day 0)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups	
Reporting group title	Menitorix/Pediarix Group Month 18
Reporting group description: -	
Reporting group title	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18
Reporting group description: -	
Reporting group title	Infanrix hexa/Meningitec Group Month 18
Reporting group description: -	
Reporting group title	Menitorix/Pediarix Group Month 30
Reporting group description: -	
Reporting group title	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30
Reporting group description: -	
Reporting group title	Infanrix hexa/Meningitec Group Month 30
Reporting group description: -	
Reporting group title	Menitorix/Pediarix Group Month 42
Reporting group description: -	
Reporting group title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42
Reporting group description: -	
Reporting group title	Infanrix hexa/Meningitec Group Month 42
Reporting group description: -	
Reporting group title	Menitorix/Pediarix Group Month 54
Reporting group description: -	
Reporting group title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54
Reporting group description: -	
Reporting group title	Infanrix hexa/Meningitec Group Month 54
Reporting group description: -	
Reporting group title	Menitorix/Pediarix Group Month 66
Reporting group description: -	
Reporting group title	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66
Reporting group description: -	
Reporting group title	Infanrix hexa/Meningitec Group Month 66
Reporting group description: -	
Reporting group title	Pooled Group Month 18
Reporting group description: -	
Reporting group title	Pooled Group Month 30
Reporting group description: -	
Reporting group title	Pooled Group Month 42
Reporting group description: -	
Reporting group title	Pooled Group Month 54
Reporting group description: -	
Reporting group title	Pooled Group Month 66

Reporting group description: -

Serious adverse events	Menitorix/Pediarix Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Meningitec Group Month 18
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 58 (0.00%)	0 / 123 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Menitorix/Pediarix Group Month 30	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Meningitec Group Month 30
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 54 (0.00%)	0 / 119 (0.00%)	0 / 57 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Menitorix/Pediarix Group Month 42	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42	Infanrix hexa/Meningitec Group Month 42
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 113 (0.00%)	0 / 56 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Menitorix/Pediarix Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Meningitec Group Month 54
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 108 (0.00%)	0 / 56 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 66
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 48 (0.00%)	0 / 104 (0.00%)	0 / 53 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0

Serious adverse events	Pooled Group Month 18	Pooled Group Month 30	Pooled Group Month 42
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 181 (0.00%)	0 / 173 (0.00%)	0 / 164 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Pooled Group Month 54	Pooled Group Month 66	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 158 (0.00%)	0 / 152 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Menitorix/Pediarix Group Month 18	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 18	Infanrix hexa/Meningitec Group Month 18
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 58 (0.00%)	0 / 123 (0.00%)	0 / 3 (0.00%)

Non-serious adverse events	Menitorix/Pediarix Group Month 30	Infanrix hexa/Infanrix IPV-Hib co-ad Group Month 30	Infanrix hexa/Meningitec Group Month 30
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 54 (0.00%)	0 / 119 (0.00%)	0 / 57 (0.00%)

Non-serious adverse events	Menitorix/Pediarix Group Month 42	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 42	Infanrix hexa/Meningitec Group Month 42
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 113 (0.00%)	0 / 56 (0.00%)

Non-serious adverse events	Menitorix/Pediarix Group Month 54	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 54	Infanrix hexa/Meningitec Group Month 54
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 50 (0.00%)	0 / 108 (0.00%)	0 / 56 (0.00%)

Non-serious adverse events	Menitorix/Pediarix Group Month 66	Infanrix hexa/Infanrix IPV/Hib co-ad Group Month 66	Infanrix hexa/Meningitec Group Month 66
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 48 (0.00%)	0 / 104 (0.00%)	0 / 53 (0.00%)

Non-serious adverse events	Pooled Group Month 18	Pooled Group Month 30	Pooled Group Month 42
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 181 (0.00%)	0 / 173 (0.00%)	0 / 164 (0.00%)

Non-serious adverse events	Pooled Group Month 54	Pooled Group Month 66	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 158 (0.00%)	0 / 152 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No non-serious adverse events were collected in this study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported