



Clinical trial results:

An open, multicentric, post-marketing surveillance (PMS) study to assess the safety and reactogenicity of GlaxoSmithKline Biologicals' DTPa-IPV/Hib vaccine administered at 3, 4, 5 and 18 months of age, in healthy infants.

Summary

EudraCT number	2015-001512-35
Trial protocol	Outside EU/EEA
Global end of trial date	23 August 2007

Results information

Result version number	v1
This version publication date	18 April 2016
First version publication date	09 July 2015

Trial information

Trial identification

Sponsor protocol code	100917
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00325156
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 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, 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	12 August 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 August 2007
Global end of trial reached?	Yes
Global end of trial date	23 August 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and reactogenicity of the DTPa-IPV/Hib vaccine.

Protection of trial subjects:

The vaccines were closely observed for at least 30 minutes following the administration of the study vaccine, with appropriate medical treatment readily available in case of a rare anaphylactic reaction.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 November 2004
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Singapore: 2590
Worldwide total number of subjects	2590
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	2590
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:

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

Period 1

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

Arms

Arm title	Infanrix-IPV+Hib Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Infanrix-IPV+Hib™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 primary doses and 1 booster dose which were administered intramuscularly into anterolateral thigh.

Investigational medicinal product name	Rotarix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in single-dose container
Routes of administration	Oral use

Dosage and administration details:

Subjects received two oral doses of Rotarix™ at 3 and 4 months of age.

Number of subjects in period 1	Infanrix-IPV+Hib Group
Started	2590
Completed	2478
Not completed	112
Consent withdrawn by subject	31
Adverse event, non-fatal	3
Lost to follow-up (complete vaccination)	41
Migrated/moved from study area	12
Unspecified	1

Lost to follow-up (Incomplete vaccination)	16
Protocol deviation	8

Baseline characteristics

Reporting groups

Reporting group title	Infanrix-IPV+Hib Group
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Reporting group description: -

Reporting group values	Infanrix-IPV+Hib Group	Total	
Number of subjects	2590	2590	
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: weeks			
arithmetic mean	13.3		
standard deviation	± 0.87	-	
Gender categorical Units: Subjects			
Female	1245	1245	
Male	1345	1345	

End points

End points reporting groups

Reporting group title	Infanrix-IPV+Hib Group
Reporting group description: -	

Primary: Number of subjects reporting solicited local and general symptoms.

End point title	Number of subjects reporting solicited local and general symptoms. ^[1]
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End point description:

End point type	Primary
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End point timeframe:

During the 4-day (Day 0-3) post-vaccination period.

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	Infanrix-IPV+Hib Group			
Subject group type	Reporting group			
Number of subjects analysed	2580			
Units: Subjects				
Any Pain, Across doses	855			
Any Redness, Across doses	907			
Any Swelling, Across doses	706			
Any Drowsiness, Across doses	929			
Any Fever (Axillary/ $\geq 37.5^{\circ}\text{C}$), Across doses	1482			
Any Irritability, Across doses	1217			
Any Loss of appetite, Across doses	1010			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited adverse events (AEs).

End point title	Number of subjects reporting any unsolicited adverse events (AEs).
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End point description:

End point type	Secondary
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End point timeframe:

During the 30-day follow up period (Day 0-29) after vaccination.

End point values	Infanrix- IPV+Hib Group			
Subject group type	Reporting group			
Number of subjects analysed	2590			
Units: Subjects				
Any AE(s)	914			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting large injection site swelling.

End point title	Number of subjects reporting large injection site swelling.
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End point description:

End point type	Secondary
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End point timeframe:

After the booster dose.

End point values	Infanrix- IPV+Hib Group			
Subject group type	Reporting group			
Number of subjects analysed	2540			
Units: Subjects				
Local swelling	10			
Diffuse swelling	1			

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects reporting any serious adverse events (SAEs).
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End point description:

End point type	Secondary
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End point timeframe:

During the entire study period.

End point values	Infanrix- IPV+Hib Group			
Subject group type	Reporting group			
Number of subjects analysed	2590			
Units: Subjects				
Any SAE(s)	380			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general adverse events (AEs): during the 4-day (Day 0–3) after vaccination.

Unsolicited local and general AEs: during the 30-day (Day 0–29) after vaccination.

Serious adverse events (SAEs): during the entire study period.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	11.0
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Reporting groups

Reporting group title	Infanrix-IPV+Hib Group
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Reporting group description: -

Serious adverse events	Infanrix-IPV+Hib Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	380 / 2590 (14.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	6 / 2590 (0.23%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Swelling			

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Milk allergy			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Balanitis			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	11 / 2590 (0.42%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Bronchial hyperreactivity			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Wheezing			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Asthmatic crisis			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epistaxis			

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Interstitial lung disease			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Rhinitis allergic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	12 / 2590 (0.46%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Foreign body trauma			
subjects affected / exposed	3 / 2590 (0.12%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	3 / 2590 (0.12%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Arthropod bite			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin laceration			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Accidental exposure			

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Burns second degree			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Laryngomalacia			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphangioma			

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac aneurysm			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	25 / 2590 (0.97%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 0		
Convulsion			
subjects affected / exposed	7 / 2590 (0.27%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Benign intracranial hypertension			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Neutropenia			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastritis			
subjects affected / exposed	5 / 2590 (0.19%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	3 / 2590 (0.12%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mouth ulceration			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			

Urticaria			
subjects affected / exposed	3 / 2590 (0.12%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Petechiae			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Swelling face			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urticaria chronic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Vesicoureteric reflux			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	87 / 2590 (3.36%)		
occurrences causally related to treatment / all	0 / 87		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	47 / 2590 (1.81%)		
occurrences causally related to treatment / all	0 / 47		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	45 / 2590 (1.74%)		
occurrences causally related to treatment / all	0 / 45		
deaths causally related to treatment / all	0 / 0		

Bronchitis				
subjects affected / exposed	20 / 2590 (0.77%)			
occurrences causally related to treatment / all	0 / 20			
deaths causally related to treatment / all	0 / 0			
Gastritis viral				
subjects affected / exposed	16 / 2590 (0.62%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	16 / 2590 (0.62%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	13 / 2590 (0.50%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Hand-foot-and-mouth disease				
subjects affected / exposed	13 / 2590 (0.50%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	13 / 2590 (0.50%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	12 / 2590 (0.46%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	10 / 2590 (0.39%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis rotavirus				

subjects affected / exposed	7 / 2590 (0.27%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Herpangina			
subjects affected / exposed	7 / 2590 (0.27%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	7 / 2590 (0.27%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Abscess limb			
subjects affected / exposed	6 / 2590 (0.23%)		
occurrences causally related to treatment / all	2 / 6		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	6 / 2590 (0.23%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			
subjects affected / exposed	6 / 2590 (0.23%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			
subjects affected / exposed	5 / 2590 (0.19%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Lobar pneumonia			
subjects affected / exposed	4 / 2590 (0.15%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			

subjects affected / exposed	4 / 2590 (0.15%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Viral skin infection			
subjects affected / exposed	4 / 2590 (0.15%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	3 / 2590 (0.12%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Croup infectious			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haematoma infection			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Perianal abscess			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abscess			

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acarodermatitis			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Conjunctivitis viral			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epstein-barr virus infection			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Exanthema subitum			

subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Folliculitis				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis bacterial				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphadenitis bacterial				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Necrotising fasciitis				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae viral laryngotracheobronchitis				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parotitis				

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection bacterial			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral pharyngitis			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Infanrix-IPV+Hib Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1482 / 2590 (57.22%)		
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	855 / 2590 (33.01%)		
occurrences (all)	855		
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	907 / 2590 (35.02%)		
occurrences (all)	907		
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	706 / 2590 (27.26%)		
occurrences (all)	706		
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	929 / 2590 (35.87%)		
occurrences (all)	929		
Fever (Axillary)			
subjects affected / exposed	1482 / 2590 (57.22%)		
occurrences (all)	1482		
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	1217 / 2590 (46.99%)		
occurrences (all)	1217		
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed	1010 / 2590 (39.00%)		
occurrences (all)	1010		
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	146 / 2590 (5.64%) 146		
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	391 / 2590 (15.10%) 391		

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