Clinical trial results:
A phase III, single-blind, randomized, controlled, multinational study for the evaluation of safety of GSK Biologicals' Haemophilus influenzae type b and Neisseria meningitidis serogroups C and Y-tetanus toxoid conjugate vaccine combined (Hib-MenCY-TT) compared to monovalent Haemophilus influenzae type b (Hib) control vaccine in healthy infants at 2, 4, 6, and 12 to 15 months of age.

Summary

EudraCT number	2005-006066-34
Trial protocol	Outside EU/EEA
Global end of trial date	12 November 2008

Results information

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	19 July 2015

Trial information

Trial identification

Sponsor protocol code	105987,105988

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00345579
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	19 June 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 October 2007
Global end of trial reached?	Yes
Global end of trial date	12 November 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Occurrence of SAEs from dose 1 up to Day 30 after dose 3 and from Dose 1 up to the day preceding the fourth dose.
Occurrence of specific adverse events of new onset of chronic illness(es), rash, and conditions prompting emergency room visits from dose 1 up to Day 30 after dose 3 and from Dose 1 up to the day preceding the fourth dose.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 September 2006
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	15 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 604
Country: Number of subjects enrolled	Mexico: 3866
Country: Number of subjects enrolled	United States: 4101
Worldwide total number of subjects	8571
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	8571

months)	
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	Primary Vaccination
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Menhibrix Primary Group

Arm description:

Subjects received 3 doses of HibMenCY-TT vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and a fourth dose of HibMenCY-TT vaccine at 12-15 months of age.

Arm type	Experimental
Investigational medicinal product name	Menhibrix ™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection in the upper right thigh.

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

Dosage and administration details:

Single dose intramuscular injection in the upper left thigh.

Arm title	ActHIB Primary Group

Arm description:

Subjects received 3 doses of Hib vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and 1 dose of Hib-OMP vaccine as a booster at 12-15 months of age.

Arm type	Experimental
Investigational medicinal product name	ActHIB®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details: Single dose intramuscular injection in the upper right thigh.	
Investigational medicinal product name	Pediarix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection in the upper left thigh.

Number of subjects in period 1	Menhibrix Primary Group	ActHIB Primary Group
Started	6414	2157
Completed	6002	2009
Not completed	412	148
Unspecified	412	148

Period 2

Period 2 title	The fourth dose vaccination
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Menhibrix Fourth Dose Group

Arm description:

Subjects received 3 doses of HibMenCY-TT vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and a fourth dose of HibMenCY-TT vaccine at 12-15 months of age.

Arm type	Experimental
Investigational medicinal product name	Menhibrix ™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection in the upper right thigh.

Investigational medicinal product name	M-M-R®II/ Varivax®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection in the upper right thigh.

Arm title	ActHIB Fourth Dose Group

Arm description:

Subjects received 3 doses of Hib vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and 1 dose of Hib-OMP vaccine as a booster at 12-15 months of age.

Arm type	Experimental
Investigational medicinal product name	ActHIB®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection in the upper right thigh.

Investigational medicinal product name	PedvaxHib®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection in the upper right thigh.

Number of subjects in period 2[1]	Menhibrix Fourth Dose Group	ActHIB Fourth Dose Group
Started	5779	1933
Completed	5667	1900
Not completed	112	33
Adverse event, serious fatal	1	-
Consent withdrawn by subject	10	1
Migrated/moved from study area	1	1
Unspecified	28	12
Lost to follow-up	72	19

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 study participants returned in time for every study visit, but they were allowed to continue the study nonetheless. The number of participants who started each study period depends on the actual rate of return of the subjects.

Baseline characteristics

Reporting groups	
Reporting group title	Menhibrix Primary Group
Reporting group description:	
Subjects received 3 doses of HibMenCY-TT vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and a fourth dose of HibMenCY-TT vaccine at 12-15 months of age.	
Reporting group title	ActHIB Primary Group
Reporting group description:	
Subjects received 3 doses of Hib vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and 1 dose of Hib-OMP vaccine as a booster at 12-15 months of age.	

Reporting group values	Menhibrix Primary Group	ActHIB Primary Group	Total
Number of subjects	6414	2157	8571
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: days			
arithmetic mean	60.9	61.1	
standard deviation	± 9.52	± 9.38	-
Gender categorical Units: Subjects			
Female	3099	1055	4154
Male	3315	1102	4417

End points

End points reporting groups

Reporting group title	Menhibrix Primary Group
Reporting group description:	
Subjects received 3 doses of HibMenCY-TT vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and a fourth dose of HibMenCY-TT vaccine at 12-15 months of age.	
Reporting group title	ActHIB Primary Group
Reporting group description:	
Subjects received 3 doses of Hib vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and 1 dose of Hib-OMP vaccine as a booster at 12-15 months of age.	
Reporting group title	Menhibrix Fourth Dose Group
Reporting group description:	
Subjects received 3 doses of HibMenCY-TT vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and a fourth dose of HibMenCY-TT vaccine at 12-15 months of age.	
Reporting group title	ActHIB Fourth Dose Group
Reporting group description:	
Subjects received 3 doses of Hib vaccine (at 2, 4 and 6 months of age), co-administered with DTPa-HBV-IPV as a primary vaccination course and 1 dose of Hib-OMP vaccine as a booster at 12-15 months of age.	

Primary: Number of subjects reporting any serious adverse events (SAEs), new onset of chronic illnesses (NOCIs), rash and unsolicited adverse events (AEs) resulting in emergency room (ER) visit after Dose 3.

End point title	Number of subjects reporting any serious adverse events (SAEs), new onset of chronic illnesses (NOCIs), rash and unsolicited adverse events (AEs) resulting in emergency room (ER) visit after Dose 3.[1]
End point description:	
End point type	Primary
End point timeframe:	
From Dose 1 (Day 0) up to Day 30 after Dose 3.	

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Menhibrix Primary Group	ActHIB Primary Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6414	2157		
Units: Subjects				
SAE	173	57		
NOCI	143	49		
Rash	621	209		
ER visit	259	91		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects reporting any serious adverse events (SAEs), new onset of chronic illnesses (NOCIs), rash and unsolicited adverse events (AEs) resulting in emergency room (ER) visit excluding the fourth dose.

End point title	Number of subjects reporting any serious adverse events (SAEs), new onset of chronic illnesses (NOCIs), rash and unsolicited adverse events (AEs) resulting in emergency room (ER) visit excluding the fourth dose.[2]

End point description:

End point type	Primary

End point timeframe:

From Dose 1 (Day 0) through but excluding the fourth dose.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Menhibrix Primary Group	ActHIB Primary Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6414	2157		
Units: Subjects				
SAE	283	98		
NOCI	229	77		
Rash	856	288		
ER visit	415	141		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any serious adverse events (SAEs), new onset of chronic illnesses (NOCIs), rash and unsolicited adverse events (AEs) resulting in emergency room (ER) visit after fourth dose vaccination.

End point title	Number of subjects reporting any serious adverse events (SAEs), new onset of chronic illnesses (NOCIs), rash and unsolicited adverse events (AEs) resulting in emergency room (ER) visit after fourth dose vaccination.

End point description:

End point type	Secondary

End point timeframe:

From fourth dose up to Day 30 after fourth dose vaccination.

End point values	Menhibrix Fourth Dose Group	ActHIB Fourth Dose Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5779	1933		
Units: Subjects				
SAE	24	9		
NOCI	44	17		
Rash	309	98		
ER visit	77	38		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any serious adverse events (SAEs), new onset of chronic illnesses (NOCIs), rash and unsolicited adverse events (AEs) resulting in emergency room (ER) visit through the end of the safety follow-up (ESFU).

End point title	Number of subjects reporting any serious adverse events (SAEs), new onset of chronic illnesses (NOCIs), rash and unsolicited adverse events (AEs) resulting in emergency room (ER) visit through the end of the safety follow-up (ESFU).

End point description:

End point type	Secondary

End point timeframe:

From fourth dose through the end of the 6-month safety follow-up (ESFU of the fourth dose phase).

End point values	Menhibrix Fourth Dose Group	ActHIB Fourth Dose Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5779	1933		
Units: Subjects				
SAE	119	36		
NOCI	135	51		
Rash	492	176		
ER visit	266	102		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Unsolicited AEs: Within 31 days (Days 0-30) after vaccination;
SAEs: During the entire study period;

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.0

Reporting groups

Reporting group title	Menhibrix Primary Group
Reporting group description: -	
Reporting group title	ActHIB Primary Group
Reporting group description: -	
Reporting group title	Menhibrix Fourth Dose Group
Reporting group description: -	
Reporting group title	ActHIB Fourth Dose Group

Reporting group description: -

Serious adverse events	Menhibrix Primary Group	ActHIB Primary Group	Menhibrix Fourth Dose Group
Total subjects affected by serious adverse events			
subjects affected / exposed	283 / 6414 (4.41%)	98 / 2157 (4.54%)	119 / 5779 (2.06%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroblastoma			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemorrhagic infarction			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
General disorders and administration site conditions			
Irritability			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia (primary)			
subjects affected / exposed	6 / 6414 (0.09%)	3 / 2157 (0.14%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden infant death syndrome			
subjects affected / exposed	4 / 6414 (0.06%)	2 / 2157 (0.09%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity (primary)			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Accidental drug intake by child			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Child abuse			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoviral upper respiratory infection			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	6 / 5779 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma (primary)			
subjects affected / exposed	4 / 6414 (0.06%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	4 / 5779 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity (primary)			
subjects affected / exposed	6 / 6414 (0.09%)	2 / 2157 (0.09%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	2 / 6414 (0.03%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia (primary)			
subjects affected / exposed	4 / 6414 (0.06%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress (primary)			
subjects affected / exposed	5 / 6414 (0.08%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	3 / 5779 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing (primary)			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing (fourth dose)			

subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apparent life threatening event			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspiration bronchial			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Injury, poisoning and procedural complications			
Accidental exposure			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic leak			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns first degree			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Burns second degree (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree (primary)			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Child maltreatment syndrome			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Eye injury			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body trauma			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured skull depressed			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury (primary)			
subjects affected / exposed	10 / 6414 (0.16%)	2 / 2157 (0.09%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury (fourth dose)			

subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Seroma			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin injury			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	3 / 6414 (0.05%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	3 / 5779 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coarctation of the aorta			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberous sclerosis			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect (primary)			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Cardiac failure congestive			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar ataxia			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion (primary)			
subjects affected / exposed	3 / 6414 (0.05%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion (primary)			
subjects affected / exposed	7 / 6414 (0.11%)	3 / 2157 (0.14%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion (fourth dose)			

subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	7 / 5779 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile spasms			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nystagmus			
subjects affected / exposed	1 / 6414 (0.02%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoid tissue hyperplasia			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node abscess			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryostenosis acquired			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain (primary)			

subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 6414 (0.02%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			

subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	4 / 6414 (0.06%)	3 / 2157 (0.14%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting (primary)			
subjects affected / exposed	2 / 6414 (0.03%)	3 / 2157 (0.14%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erysipelas			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Henoch-schonlein purpura			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			

subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypoglycemia			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess (fourth dose)			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess (primary)			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acarodermatitis			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchiolitis (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	10 / 5779 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis (primary)			
subjects affected / exposed	57 / 6414 (0.89%)	11 / 2157 (0.51%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 57	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia (fourth dose)			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia (primary)			
subjects affected / exposed	18 / 6414 (0.28%)	12 / 2157 (0.56%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 18	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Campylobacter gastroenteritis (primary)			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis (primary)			

subjects affected / exposed	3 / 6414 (0.05%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious (primary)			
subjects affected / exposed	4 / 6414 (0.06%)	3 / 2157 (0.14%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	4 / 5779 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis (primary)			
subjects affected / exposed	51 / 6414 (0.80%)	18 / 2157 (0.83%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 51	0 / 18	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Gastroenteritis (fourth dose)			

subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	33 / 5779 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 33
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus (primary)			
subjects affected / exposed	10 / 6414 (0.16%)	3 / 2157 (0.14%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral (primary)			
subjects affected / exposed	1 / 6414 (0.02%)	2 / 2157 (0.09%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Group b streptococcus neonatal sepsis			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIV infection			

subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza (primary)			
subjects affected / exposed	0 / 6414 (0.00%)	2 / 2157 (0.09%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia (primary)			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangioma (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	1 / 6414 (0.02%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media (primary)			

subjects affected / exposed	9 / 6414 (0.14%)	4 / 2157 (0.19%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pertussis			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	2 / 6414 (0.03%)	2 / 2157 (0.09%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia (primary)			
subjects affected / exposed	17 / 6414 (0.27%)	4 / 2157 (0.19%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Pneumonia (fourth dose)			
subjects affected / exposed	4 / 6414 (0.06%)	2 / 2157 (0.09%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			

subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral (primary)			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	4 / 6414 (0.06%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis (primary)			
subjects affected / exposed	18 / 6414 (0.28%)	3 / 2157 (0.14%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 18	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection (primary)			
subjects affected / exposed	5 / 6414 (0.08%)	4 / 2157 (0.19%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory tract infection viral			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection (primary)			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	4 / 5779 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess (primary)			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis (primary)			

subjects affected / exposed	1 / 6414 (0.02%)	2 / 2157 (0.09%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection (primary)			
subjects affected / exposed	5 / 6414 (0.08%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	2 / 5779 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection (primary)			
subjects affected / exposed	12 / 6414 (0.19%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection (primary)			

subjects affected / exposed	11 / 6414 (0.17%)	3 / 2157 (0.14%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	5 / 5779 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral skin infection			
subjects affected / exposed	2 / 6414 (0.03%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection (primary)			
subjects affected / exposed	2 / 6414 (0.03%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval abscess			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia (forth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	1 / 5779 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Acidosis			
subjects affected / exposed	1 / 6414 (0.02%)	0 / 2157 (0.00%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration (primary)			
subjects affected / exposed	20 / 6414 (0.31%)	7 / 2157 (0.32%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dehydration (fourth dose)			
subjects affected / exposed	0 / 6414 (0.00%)	0 / 2157 (0.00%)	9 / 5779 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	2 / 6414 (0.03%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 6414 (0.00%)	1 / 2157 (0.05%)	0 / 5779 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ActHIB Fourth Dose Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	36 / 1933 (1.86%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuroblastoma			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic infarction			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Irritability			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pyrexia (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden infant death syndrome			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Accidental drug intake by child			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Child abuse			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenoviral upper respiratory infection			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Apnoea			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthma (fourth dose)			
subjects affected / exposed	2 / 1933 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Asthma (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial hyperreactivity (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial hyperreactivity (primary)			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory disorder			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory distress (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory distress (fourth dose)			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stridor			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wheezing (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wheezing (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung disorder			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Apparent life threatening event			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Aspiration bronchial			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accidental exposure			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Anastomotic leak				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burns first degree				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burns second degree (fourth dose)				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burns second degree (primary)				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Child maltreatment syndrome				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye injury				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foreign body trauma				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fractured skull depressed				

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury (fourth dose)			
subjects affected / exposed	2 / 1933 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seroma			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin injury			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin laceration			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fracture			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fractured base			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coarctation of the aorta			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tuberous sclerosis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular septal defect (primary)			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular septal defect (fourth dose)			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Ataxia			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebellar ataxia			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion (fourth dose)			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depressed level of consciousness			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Epilepsy				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile convulsion (primary)				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile convulsion (fourth dose)				
subjects affected / exposed	2 / 1933 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotonia				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infantile spasms				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nystagmus				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukocytosis				

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoid tissue hyperplasia			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymph node abscess			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dacryostenosis acquired			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus			

subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia, obstructive				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intussusception				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting (primary)				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting (fourth dose)				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Erysipelas				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema multiforme				
subjects affected / exposed	0 / 1933 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Henoch-schonlein purpura				

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash papular			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hypoglycemia			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abscess neck			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acarodermatitis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis (fourth dose)			
subjects affected / exposed	3 / 1933 (0.16%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Campylobacter gastroenteritis (primary)			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Campylobacter gastroenteritis (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Croup infectious (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Croup infectious (fourth dose)			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Folliculitis			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis (fourth dose)			
subjects affected / exposed	11 / 1933 (0.57%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral (fourth dose)			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Group b streptococcus neonatal sepsis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HIV infection			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lobar pneumonia (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphangioma (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis viral			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis media (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media (fourth dose)			
subjects affected / exposed	2 / 1933 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Perirectal abscess			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pertussis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia (primary)			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral (fourth dose)			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchiolitis (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchiolitis (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection (primary)			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection viral			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess (fourth dose)			

subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheitis (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheitis (fourth dose)			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Typhoid fever			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection (fourth dose)			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicella			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection (fourth dose)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral skin infection			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection (fourth dose)			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vulval abscess			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lobar pneumonia (forth dose)			

subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	1 / 1933 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration (primary)			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration (fourth dose)			
subjects affected / exposed	2 / 1933 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	0 / 1933 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Menhibrix Primary Group	ActHIB Primary Group	Menhibrix Fourth Dose Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1409 / 6414 (21.97%)	288 / 2157 (13.35%)	492 / 5779 (8.51%)
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	856 / 6414 (13.35%)	288 / 2157 (13.35%)	492 / 5779 (8.51%)
occurrences (all)	856	288	492

Non-serious adverse events	ActHIB Fourth Dose Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	299 / 1933 (15.47%)		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	176 / 1933 (9.11%)		
occurrences (all)	176		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 January 2007	1. Based on feedback from the FDA, GSK will provide Prevnar (4th dose), M-M-R II, and Varivax as study vaccines. M-M-R II and Varivax must be given according to current US labeling and ACIP recommendations (i.e. M-M-R II must be administered between 12 to 15 months of age. Varivax should be administered between 12 to 18 months of age). It is preferred that subjects receive Prevnar concomitantly at the booster phase between 12 to 15 months of age according to current US labeling and ACIP recommendations. It is the preference for subjects to receive Prevnar, M-M-R II and Varivax with the booster dose of Hib-MenCYTT/PedvaxHIB. 2. At the booster vaccination visit, all centers will use PedvaxHIB as the Hib control (i.e. ActHIB will not be used).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported