Clinical trial results:
A PHASE 4, RANDOMIZED, OPEN-LABEL TRIAL TO ASSESS THE IMPACT OF PROPHYLACTIC ANTIPYRETIC MEDICATION ON THE IMMUNOGENICITY OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE GIVEN WITH ROUTINE PEDIATRIC VACCINATIONS IN HEALTHY INFANTS

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2010-022303-22
Trial protocol	PL
Global end of trial date	16 January 2013

Results information

Result version number	v2 (current)
This version publication date	28 July 2016
First version publication date	01 August 2015
Version creation reason	• Correction of full data set reporting periods and duplicate AEs in their data

Trial information

Trial identification

Sponsor protocol code	B1851047

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01392378
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Clinical Trials.gov Call Centre, Pfizer Inc., 001 8007181021, ClinicalTrials.govCallCentre@pfizer.com
Scientific contact	Clinical Trials.gov Call Centre, Pfizer Inc., 001 8007181021, ClinicalTrials.govCallCentre@pfizer.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 September 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 January 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the impact of prophylactic paracetamol or ibuprofen administration on the immunogenicity of 13-valent pneumococcal conjugate vaccine (13vPnC) as measured by serotype-specific immunoglobulin G (IgG) geometric mean concentrations (GMCs) after completion of the infant series.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed; in particular, those affording greater protection to the safety of study subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 August 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 908
Worldwide total number of subjects	908
EEA total number of subjects	908

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	908
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:

This study was conducted at 14 sites in Poland.Total 908 subjects were enrolled between 05 August 2011 to 16 January 2013. Two (2) subjects were screened but not enrolled.

Period 1

Period 1 title	Infant Series
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant

Arm description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (greater than or equal to [>=]56 to less than or equal to [<=]98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age along with paracetamol at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 milliliter (mL) dose of 13vPnC at 2 months (>= 56 to <= 98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Paracetamol suspension 15 milligram per kilogram (mg/kg) at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol.

Arm title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant

Arm description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42

days after Dose 2, infant series) of age, along with ibuprofen at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 2 months (>= 56 to <= 98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer’s instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	Ibuprofen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Ibuprofen suspension 10 mg/kg at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen.

Arm title	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant

Arm description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer’s instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age, along with paracetamol immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 2 months (>= 56 to <= 98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer’s instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Paracetamol suspension 15 mg/kg immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Arm title	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant

Arm description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age, along with ibuprofen 10 mg/kg orally immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 2 months (>= 56 to <= 98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	Ibuprofen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Ibuprofen suspension 10 mg/kg immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Arm title	13vPnC + INFANRIX Hexa:Infant

Arm description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age.

Arm type	Control
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer’s instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age.

Number of subjects in period 1	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Started	173	176	172
Vaccinated Dose 1	173	176	172
Vaccinated Dose 2	171	174	172
Vaccinated Dose 3	170	174	172
Completed	169	174	172
Not completed	4	2	0
Withdrawal by parent	4	1	-
Adverse event	-	-	-
Protocol Violation	-	1	-
Lost to follow-up	-	-	-

Number of subjects in period 1	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant	13vPnC + INFANRIX Hexa:Infant
Started	177	210
Vaccinated Dose 1	177	210
Vaccinated Dose 2	177	210
Vaccinated Dose 3	176	210
Completed	175	210
Not completed	2	0
Withdrawal by parent	-	-
Adverse event	1	-
Protocol Violation	-	-
Lost to follow-up	1	-

Period 2

Period 2 title	After Infant Series
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily:After Infant

Arm description:

Included subjects who received 3 open-label doses of 13vPnC and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series, along with paracetamol at 6 to 8 hours after vaccination and 6 to 8 hours after first dose of paracetamol.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:After Infant

Arm description:

Included subjects who received 3 open-label doses of 13vPnCn and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series, along with ibuprofen at 6 to 8 hours after vaccination and 6 to 8 hours after first dose of ibuprofen.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:After Infant

Arm description:

Included subjects who received 3 open-label doses of 13vPnC and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series, along with paracetamol immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:After Infant

Arm description:

Included subjects who received 3 open-label doses of 13vPnC and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series, along with ibuprofen immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC + INFANRIX Hexa:After Infant

Arm description:

Included subjects who received 3 open-label doses of 13vPnC and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily:After Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:After Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:After Infant
Started	169	174	172
Completed	169	173	170
Not completed	0	1	2
Withdrawal by parent	-	1	1
Lost to follow-up	-	-	1

Number of subjects in period 2	13vPnC + INFANRIX Hexa + Ibuprofen	13vPnC + INFANRIX Hexa:After Infant

	Thrice Daily:After Infant	
Started	175	210
Completed	175	209
Not completed	0	1
Withdrawal by parent	-	1
Lost to follow-up	-	-

Period 3

Period 3 title	Toddler Dose
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler

Arm description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with paracetamol at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Paracetamol suspension 15 mg/kg at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol.

Arm title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler

Arm description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at

11 to 12 months (366 to 425 days of age, toddler dose) of age, along with ibuprofen suspension at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa intramuscularly as per manufacturer’s instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	Ibuprofen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Ibuprofen suspension 10 mg/kg at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen.

Arm title	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler

Arm description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer’s instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with paracetamol immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer’s instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Paracetamol suspension 15 mg/kg immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Arm title	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler

Arm description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with ibuprofen immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	Ibuprofen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Ibuprofen suspension 10 mg/kg immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Arm title	13vPnC + INFANRIX Hexa:Toddler

Arm description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Arm type	Control
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Investigational medicinal product name	INFANRIX hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received INFANRIX hexa as per manufacturer’s instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Number of subjects in period 3	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Started	169	173	170
Completed	169	172	170
Not completed	0	1	0
Withdrawal by parent	-	1	-
Lost to follow-up	-	-	-

Number of subjects in period 3	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler	13vPnC + INFANRIX Hexa:Toddler
Started	175	209
Completed	173	208
Not completed	2	1
Withdrawal by parent	1	1
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Reporting group description:	
Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (greater than or equal to [>=]56 to less than or equal to [<=]98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age along with paracetamol at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol.	
Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Reporting group description:	
Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age, along with ibuprofen at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen.	
Reporting group title	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Reporting group description:	
Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age, along with paracetamol immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.	
Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Reporting group description:	
Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age, along with ibuprofen 10 mg/kg orally immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.	
Reporting group title	13vPnC + INFANRIX Hexa:Infant
Reporting group description:	
Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age.	

Reporting group values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects	173	176	172
Age categorical			
Units: Subjects			
Age continuous			
Units: days			
arithmetic mean	65.1	66.5	65.6
standard deviation	± 9.5	± 10.1	± 9.7
Gender categorical			
Units: Subjects			
Female	87	89	75
Male	86	87	97

Reporting group values	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant	13vPnC + INFANRIX Hexa:Infant	Total
Number of subjects	177	210	908

Age categorical Units: Subjects			

Age continuous Units: days			
arithmetic mean	66.4	65.6	
standard deviation	± 10.3	± 9.4	-
Gender categorical Units: Subjects			
Female	79	98	428
Male	98	112	480

End points reporting groups

Reporting group title	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant

Reporting group description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (greater than or equal to [>=]56 to less than or equal to [<=]98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age along with paracetamol at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol.

Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant

Reporting group description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age, along with ibuprofen at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen.

Reporting group title	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant

Reporting group description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age, along with paracetamol immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant

Reporting group description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1),and 4 months (28 to 42 days after Dose 2, infant series) of age, along with ibuprofen 10 mg/kg orally immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Reporting group title	13vPnC + INFANRIX Hexa:Infant

Reporting group description:

Subjects received open-label 13vPnC and INFANRIX hexa as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), and 4 months (28 to 42 days after Dose 2, infant series) of age.

Reporting group title	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily:After Infant

Reporting group description:

Included subjects who received 3 open-label doses of 13vPnC and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series, along with paracetamol at 6 to 8 hours after vaccination and 6 to 8 hours after first dose of paracetamol.

Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:After Infant

Reporting group description:

Included subjects who received 3 open-label doses of 13vPnCn and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series, along with ibuprofen at 6 to 8 hours after vaccination and 6 to 8 hours after first dose of ibuprofen.

Reporting group title	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:After Infant

Reporting group description:

Included subjects who received 3 open-label doses of 13vPnC and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series, along with paracetamol immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:After Infant

Reporting group description:

Included subjects who received 3 open-label doses of 13vPnC and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series, along with ibuprofen immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Reporting group title	13vPnC + INFANRIX Hexa:After Infant

Reporting group description:

Included subjects who received 3 open-label doses of 13vPnC and INFANRIX hexa as per manufacturer's instructions 28 to 42 days apart in infant series.

Reporting group title	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler

Reporting group description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with paracetamol at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol.

Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler

Reporting group description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with ibuprofen suspension at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen.

Reporting group title	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler

Reporting group description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with paracetamol immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler

Reporting group description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with ibuprofen immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Reporting group title	13vPnC + INFANRIX Hexa:Toddler

Reporting group description:

Subjects received open-label dose of 13vPnC and INFANRIX hexa as per manufacturer's instructions at 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Subject analysis set title	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received open-label 0.5 mL dose of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 2 months (greater than or equal to [>=]56 to less than or equal to [<=]98 days of age), 3 months (28 to 42 days after Dose 1), 4 months (28 to 42 days after Dose 2, infant series) and 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with paracetamol suspension 15 mg/kg orally at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol.

Subject analysis set title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received open-label 0.5 mL dose of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), 4 months (28 to 42 days after Dose 2, infant series) and 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with ibuprofen suspension 10 mg/kg orally at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen.

Subject analysis set title	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received open-label 0.5 mL dose of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), 4 months (28 to 42 days after Dose 2, infant series) and 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with paracetamol suspension 15 mg/kg orally immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of paracetamol.

Subject analysis set title	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received open-label 0.5 mL dose of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), 4 months (28 to 42 days after Dose 2, infant series) and 11 to 12 months (366 to 425 days of age, toddler dose) of age, along with ibuprofen suspension 10 mg/kg orally immediately after vaccination, 6 to 8 hours after vaccination and 6 to 8 hours after last dose of ibuprofen.

Subject analysis set title	13vPnC + INFANRIX Hexa

Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received open-label 0.5 mL dose of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 2 months (>=56 to <=98 days of age), 3 months (28 to 42 days after Dose 1), 4 months (28 to 42 days after Dose 2, infant series) and 11 to 12 months (366 to 425 days of age, toddler dose) of age.

Primary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Infant Series

End point description:

Antibody geometric least squares (LS) mean concentrations (GMCs) for 13 pneumococcal serotypes (4, 6B, 9V, 14, 18C, 19F, 23F, 1, 3, 5, 6A, 7F and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95 percent (%) confidence interval (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. Modified intent-to-treat (mITT) infant immunogenicity set: all eligible subjects who had >=1 valid,determinate assay result, 56-98 days of age at Vaccination 1, received antipyretic regimen as per randomization,may have had received additional anti-pyretic medication,had blood drawn within specified time frames,had no major protocol violations. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Primary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138[1]	155[2]	148[3]	147[4]
Units: microgram per milliliter (mcg/mL)				
geometric mean (confidence interval 95%)				
4 (n = 137, 155, 148, 146, 210)	1.64 (1.44 to 1.87)	1.99 (1.76 to 2.25)	1.48 (1.31 to 1.68)	2.07 (1.82 to 2.34)
6B (n = 136, 155, 148, 146, 210)	0.68 (0.55 to 0.83)	0.91 (0.76 to 1.1)	0.56 (0.46 to 0.68)	0.9 (0.74 to 1.09)
9V (n = 138, 155, 148, 147, 210)	1.13 (1.01 to 1.27)	1.45 (1.3 to 1.61)	1.17 (1.05 to 1.3)	1.4 (1.26 to 1.56)
14 (n = 138, 155, 148, 147, 210)	4.45 (3.76 to 5.26)	4.73 (4.04 to 5.54)	4.75 (4.04 to 5.58)	5.26 (4.48 to 6.19)
18C (n = 138, 155, 148, 147, 210)	1.47 (1.29 to 1.66)	1.73 (1.54 to 1.95)	1.25 (1.11 to 1.42)	1.75 (1.55 to 1.97)
19F (n = 138, 155, 148, 147, 210)	1.78 (1.57 to 2.02)	2.3 (2.04 to 2.59)	1.59 (1.41 to 1.8)	2.04 (1.81 to 2.31)
23F (n= 137, 155, 148, 146, 210)	0.85 (0.72 to 1)	1.19 (1.02 to 1.4)	0.73 (0.62 to 0.86)	1.07 (0.91 to 1.26)
1 (n = 138, 155, 148, 147, 210)	1.12 (0.98 to 1.27)	1.5 (1.33 to 1.69)	1.02 (0.9 to 1.16)	1.29 (1.14 to 1.47)
3 (n = 138, 155, 148, 147, 210)	0.71 (0.63 to 0.79)	0.83 (0.75 to 0.93)	0.57 (0.51 to 0.64)	0.84 (0.75 to 0.94)
5 (n = 137, 155, 148, 146, 210)	0.79 (0.69 to 0.91)	0.98 (0.86 to 1.11)	0.63 (0.55 to 0.72)	0.9 (0.78 to 1.02)

6A (n = 138, 155, 148, 146, 210)	0.97 (0.84 to 1.13)	1.25 (1.09 to 1.44)	0.85 (0.74 to 0.98)	1.22 (1.06 to 1.41)
7F (n = 138, 155, 148, 146, 210)	1.94 (1.74 to 2.16)	2.22 (2.01 to 2.46)	1.83 (1.65 to 2.03)	2.28 (2.06 to 2.53)
19A (n = 137, 155, 148, 146, 210)	2.7 (2.38 to 3.07)	3.39 (3.01 to 3.82)	2.53 (2.24 to 2.86)	3.14 (2.77 to 3.55)

Notes:

[1] - Subjects who were evaluable for this measure.

[2] - Subjects who were evaluable for this measure.

[3] - Subjects who were evaluable for this measure.

[4] - Subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	210[5]			
Units: microgram per milliliter (mcg/mL)				
geometric mean (confidence interval 95%)				
4 (n = 137, 155, 148, 146, 210)	2.02 (1.82 to 2.25)			
6B (n = 136, 155, 148, 146, 210)	0.81 (0.69 to 0.96)			
9V (n = 138, 155, 148, 147, 210)	1.31 (1.19 to 1.43)			
14 (n = 138, 155, 148, 147, 210)	5.38 (4.7 to 6.16)			
18C (n = 138, 155, 148, 147, 210)	1.54 (1.39 to 1.7)			
19F (n = 138, 155, 148, 147, 210)	1.99 (1.8 to 2.2)			
23F (n= 137, 155, 148, 146, 210)	1.04 (0.91 to 1.19)			
1 (n = 138, 155, 148, 147, 210)	1.25 (1.12 to 1.38)			
3 (n = 138, 155, 148, 147, 210)	0.88 (0.79 to 0.96)			
5 (n = 137, 155, 148, 146, 210)	0.81 (0.73 to 0.91)			
6A (n = 138, 155, 148, 146, 210)	1.1 (0.97 to 1.24)			
7F (n = 138, 155, 148, 146, 210)	2.15 (1.97 to 2.34)			
19A (n = 137, 155, 148, 146, 210)	3.02 (2.72 to 3.34)			

Notes:

[5] - Subjects who were evaluable for this measure.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol (PCM) twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant

Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0856 [6]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.96

Notes:

[6] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen (IBF) twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8546 [7]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.16

Notes:

[7] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0012 [8]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.73

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.86

Notes:

[8] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [9]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.2

Notes:

[9] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2412 [10]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.08

Notes:

[10] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4548 [11]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.44

Notes:

[11] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0093 [12]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.88

Notes:

[12] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant

Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [13]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.42

Notes:

[13] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1749 [14]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1

Notes:

[14] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3121 [15]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.27

Notes:

[15] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1351 [16]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.03

Notes:

[16] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [17]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.24

Notes:

[17] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2158 [18]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.03

Notes:

[18] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3279 [19]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.08

Notes:

[19] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant

Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2472 [20]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.09

Notes:

[20] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [21]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.21

Notes:

[21] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6193 [22]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.95

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.12

Notes:

[22] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3121 [23]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.32

Notes:

[23] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group..

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0191 [24]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.96

Notes:

[24] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [25]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.33

Notes:

[25] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2412 [26]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.05

Notes:

[26] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant

Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3121 [27]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.35

Notes:

[27] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0135 [28]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	0.94

Notes:

[28] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [29]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.21

Notes:

[29] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1749 [30]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1

Notes:

[30] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3121 [31]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.41

Notes:

[31] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0038 [32]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.86

Notes:

[32] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [33]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.27

Notes:

[33] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant v 13vPnC + INFANRIX Hexa:Infant

Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2412 [34]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.06

Notes:

[34] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2053 [35]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	1.41

Notes:

[35] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0241 [36]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.82

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.96

Notes:

[36] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [37]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.22

Notes:

[37] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0732 [38]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.94

Notes:

[38] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.609 [39]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.1

Notes:

[39] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [40]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	0.76

Notes:

[40] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant

Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [41]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.11

Notes:

[41] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7828 [42]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.16

Notes:

[42] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2053 [43]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.21

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	1.43

Notes:

[43] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0093 [44]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.92

Notes:

[44] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [45]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.31

Notes:

[45] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2412 [46]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.07

Notes:

[46] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3121 [47]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.37

Notes:

[47] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant

Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0135 [48]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.93

Notes:

[48] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [49]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.34

Notes:

[49] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2412 [50]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.03

Notes:

[50] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6652 [51]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.18

Notes:

[51] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0275 [52]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.98

Notes:

[52] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [53]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.21

Notes:

[53] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2412 [54]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.06

Notes:

[54] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant

Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3121 [55]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.32

Notes:

[55] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0387 [56]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.99

Notes:

[56] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8414 [57]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.04

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.22

Notes:

[57] - P-values were adjusted using false discovery rate procedure.

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level Greater Than or Equal to (>=)0.35 Microgram Per Milliliter (Mcg/mL) 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level Greater Than or Equal to (>=)0.35 Microgram Per Milliliter (Mcg/mL) 1 Month After the Infant Series

End point description:

Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95% confidence interval (CI) for 13 pneumococcal serotypes (4, 6B, 9V, 14, 18C, 19F, 23F, 1, 3, 5, 6A, 7F and 19A) are presented. Exact 2-sided CI based on the observed proportion of subjects. mITT infant immunogenicity population. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138[58]	155[59]	148[60]	147[61]
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n = 137, 155, 148, 146, 210)	96.4 (91.69 to 98.8)	97.4 (93.52 to 99.29)	96.6 (92.29 to 98.89)	97.3 (93.13 to 99.25)
6B (n = 136, 155, 148, 146, 210)	72.8 (64.5 to 80.07)	80 (72.83 to 85.99)	61.5 (53.14 to 69.36)	79.5 (71.98 to 85.69)
9V (n = 138, 155, 148, 147, 210)	94.2 (88.9 to 97.46)	99.4 (96.46 to 99.98)	95.9 (91.39 to 98.5)	95.9 (91.33 to 98.49)
14 (n = 138, 155, 148, 147, 210)	100 (97.36 to 100)	98.7 (95.42 to 99.84)	99.3 (96.29 to 99.98)	98.6 (95.17 to 99.83)
18C (n = 138, 155, 148, 147, 210)	96.4 (91.75 to 98.81)	97.4 (93.52 to 99.29)	95.3 (90.5 to 98.08)	95.9 (91.33 to 98.49)
19F (n = 138, 155, 148, 147, 210)	97.1 (92.74 to 99.2)	99.4 (96.46 to 99.98)	95.3 (90.5 to 98.08)	96.6 (92.24 to 98.89)
23F (n = 137, 155, 148, 146, 210)	86.1 (79.19 to 91.44)	90.3 (84.54 to 94.48)	74.3 (66.5 to 81.15)	88.4 (82.01 to 93.07)
1 (n = 138, 155, 148, 147, 210)	94.2 (88.9 to 97.46)	97.4 (93.52 to 99.29)	90.5 (84.64 to 94.73)	94.6 (89.56 to 97.62)
3 (n = 138, 155, 148, 147, 210)	83.3 (76.05 to 89.13)	89.7 (83.78 to 93.98)	81.1 (73.83 to 87.05)	88.4 (82.13 to 93.12)
5 (n = 137, 155, 148, 146, 210)	84.7 (77.53 to 90.25)	91 (85.31 to 94.97)	76.4 (68.68 to 82.94)	89.7 (83.62 to 94.13)

6A (n = 138, 155, 148, 146, 210)	86.2 (79.34 to 91.5)	92.3 (86.87 to 95.94)	83.1 (76.08 to 88.76)	91.8 (86.08 to 95.68)
7F (n = 138, 155, 148, 146, 210)	100 (97.36 to 100)	99.4 (96.46 to 99.98)	97.3 (93.22 to 99.26)	100 (97.51 to 100)
19A (n = 137, 155, 148, 146, 210)	98.5 (94.83 to 99.82)	99.4 (96.46 to 99.98)	98 (94.19 to 99.58)	99.3 (96.24 to 99.98)

Notes:

[58] - Subjects who were evaluable for this measure.

[59] - Subjects who were evaluable for this measure.

[60] - Subjects who were evaluable for this measure.

[61] - Subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	210[62]			
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n = 137, 155, 148, 146, 210)	98.1 (95.2 to 99.48)			
6B (n = 136, 155, 148, 146, 210)	77.6 (71.37 to 83.07)			
9V (n = 138, 155, 148, 147, 210)	96.2 (92.63 to 98.34)			
14 (n = 138, 155, 148, 147, 210)	99.5 (97.38 to 99.99)			
18C (n = 138, 155, 148, 147, 210)	96.7 (93.25 to 98.65)			
19F (n = 138, 155, 148, 147, 210)	97.6 (94.53 to 99.22)			
23F (n = 137, 155, 148, 146, 210)	88.1 (82.93 to 92.15)			
1 (n = 138, 155, 148, 147, 210)	94.3 (90.23 to 97.01)			
3 (n = 138, 155, 148, 147, 210)	91 (86.23 to 94.46)			
5 (n = 137, 155, 148, 146, 210)	84.3 (78.65 to 88.93)			
6A (n = 138, 155, 148, 146, 210)	91.9 (87.36 to 95.21)			
7F (n = 138, 155, 148, 146, 210)	99.5 (97.38 to 99.99)			
19A (n = 137, 155, 148, 146, 210)	100 (98.26 to 100)			

Notes:

[62] - Subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Toddler Dose

End point description:

Antibody geometric LS mean concentrations (GMCs) for 13 pneumococcal serotypes (4, 6B, 9V, 14, 18C, 19F, 23F, 1, 3, 5, 6A, 7F and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. mITT toddler immunogenicity set: eligible subjects who had >=1 valid,determinate assay result, 56-98 days of age at Vaccination 1, received antipyretic regimen as per randomization, received all vaccinations, may have had received additional anti-pyretic medication, had blood drawn within specified time frames, had no major protocol violations. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm respectively. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	130[63]	144[64]	143[65]	139[66]
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n = 130, 144, 143, 139, 206)	3.07 (2.66 to 3.54)	3.43 (3 to 3.93)	2.97 (2.6 to 3.41)	3.43 (2.99 to 3.94)
6B (n = 130, 144, 143, 139, 206)	6.7 (5.76 to 7.78)	8.01 (6.94 to 9.24)	6.38 (5.53 to 7.36)	7.3 (6.31 to 8.44)
9V (n = 130, 144, 143, 139, 206)	2.15 (1.93 to 2.4)	2.23 (2.01 to 2.47)	2.17 (1.96 to 2.41)	2.12 (1.91 to 2.35)
14 (n = 130, 144, 143, 139, 206)	8.1 (7.04 to 9.31)	8.4 (7.36 to 9.59)	7.95 (6.96 to 9.08)	9.12 (7.96 to 10.43)
18C (n = 130, 144, 143, 139, 206)	1.35 (1.2 to 1.53)	1.68 (1.49 to 1.88)	1.36 (1.21 to 1.53)	1.63 (1.45 to 1.84)
19F (n = 130, 144, 143, 139, 206)	8.41 (7.17 to 9.87)	8.99 (7.72 to 10.46)	7.53 (6.47 to 8.76)	8.02 (6.88 to 9.36)
23F (n = 130, 144, 142, 139, 206)	2.34 (2.01 to 2.73)	2.96 (2.56 to 3.43)	2.37 (2.05 to 2.75)	2.86 (2.47 to 3.32)
1 (n = 130, 144, 143, 139, 206)	2.8 (2.47 to 3.17)	3.22 (2.85 to 3.62)	2.66 (2.36 to 3)	3.12 (2.76 to 3.52)
3 (n = 129, 144, 143, 138, 203)	0.46 (0.4 to 0.52)	0.54 (0.47 to 0.61)	0.46 (0.4 to 0.52)	0.49 (0.42 to 0.55)
5 (n = 130, 144, 143, 139, 206)	2.33 (2.07 to 2.63)	2.75 (2.46 to 3.07)	2.4 (2.15 to 2.69)	2.62 (2.33 to 2.93)
6A (n = 130, 144, 143, 139, 206)	5.12 (4.48 to 5.86)	5.73 (5.04 to 6.5)	5.27 (4.64 to 5.99)	5.36 (4.7 to 6.1)
7F (n = 130, 144, 142, 139, 206)	3.79 (3.42 to 4.19)	3.89 (3.54 to 4.28)	3.56 (3.23 to 3.92)	3.97 (3.6 to 4.38)
19A (n = 129, 144, 142, 139, 206)	7.11 (6.22 to 8.12)	7.99 (7.04 to 9.06)	7.31 (6.43 to 8.3)	7.35 (6.47 to 8.36)

Notes:

[63] - Subjects who were evaluable for this measure.

[64] - Subjects who were evaluable for this measure.

[65] - Subjects who were evaluable for this measure.

[66] - Subjects who were evaluable for this measure.

End point values	13vPnC +			

	INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	206[67]			
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n = 130, 144, 143, 139, 206)	3.1 (2.77 to 3.48)			
6B (n = 130, 144, 143, 139, 206)	7.08 (6.28 to 7.98)			
9V (n = 130, 144, 143, 139, 206)	2.16 (1.99 to 2.36)			
14 (n = 130, 144, 143, 139, 206)	9.1 (8.15 to 10.17)			
18C (n = 130, 144, 143, 139, 206)	1.59 (1.44 to 1.75)			
19F (n = 130, 144, 143, 139, 206)	7.95 (7 to 9.02)			
23F (n = 130, 144, 142, 139, 206)	2.75 (2.43 to 3.1)			
1 (n = 130, 144, 143, 139, 206)	3.04 (2.75 to 3.35)			
3 (n = 129, 144, 143, 138, 203)	0.54 (0.48 to 0.6)			
5 (n = 130, 144, 143, 139, 206)	2.84 (2.59 to 3.12)			
6A (n = 130, 144, 143, 139, 206)	5.52 (4.97 to 6.14)			
7F (n = 130, 144, 142, 139, 206)	3.98 (3.67 to 4.31)			
19A (n = 129, 144, 142, 139, 206)	7.71 (6.94 to 8.57)			

Notes:

[67] - Subjects who were evaluable for this measure.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.935 [68]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.19

Notes:

[68] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [69]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.32

Notes:

[69] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6922 [70]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.14

Notes:

[70] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [71]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.32

Notes:

[71] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler v 13vPnC + INFANRIX Hexa:Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6915 [72]
Method	General linear model
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.15

Notes:

[72] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [73]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.13

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.36

Notes:

[73] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4389 [74]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.09

Notes:

[74] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [75]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.24

Notes:

[75] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.935 [76]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.14

Notes:

[76] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [77]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.18

Notes:

[77] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler

Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.943 [78]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.15

Notes:

[78] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [79]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.12

Notes:

[79] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5167 [80]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.89

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.06

Notes:

[80] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [81]
Method	General linear model
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.1

Notes:

[81] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2514 [82]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.04

Notes:

[82] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9872 [83]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.19

Notes:

[83] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2582 [84]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1

Notes:

[84] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler

Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [85]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.23

Notes:

[85] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2514 [86]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1

Notes:

[86] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [87]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.2

Notes:

[87] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6915 [88]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.3

Notes:

[88] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [89]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.38

Notes:

[89] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler v 13vPnC + INFANRIX Hexa:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6922 [90]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.15

Notes:

[90] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9872 [91]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.23

Notes:

[91] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler v 13vPnC + INFANRIX Hexa:Toddler

Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3609 [92]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.04

Notes:

[92] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [93]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.3

Notes:

[93] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2514 [94]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.86

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.05

Notes:

[94] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [95]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.26

Notes:

[95] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6304 [96]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.08

Notes:

[96] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [97]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.24

Notes:

[97] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2514 [98]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.03

Notes:

[98] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler

Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [99]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.2

Notes:

[99] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2582 [100]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.01

Notes:

[100] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9279 [101]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.99

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.18

Notes:

[101] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2514 [102]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.01

Notes:

[102] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [103]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.07

Notes:

[103] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1424 [104]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.96

Notes:

[104] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [105]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.12

Notes:

[105] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler

Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2514 [106]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.98

Notes:

[106] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [107]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.07

Notes:

[107] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6304 [108]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.1

Notes:

[108] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [109]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.22

Notes:

[109] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6922 [110]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.13

Notes:

[110] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [111]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.15

Notes:

[111] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6572 [112]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.08

Notes:

[112] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler

Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [113]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.11

Notes:

[113] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2514 [114]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.01

Notes:

[114] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9872 [115]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.13

Notes:

[115] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6304 [116]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.09

Notes:

[116] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7918 [117]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.22

Notes:

[117] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6922 [118]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.12

Notes:

[118] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of IgG GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9765 [119]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.13

Notes:

[119] - P-values were adjusted using false discovery rate procedure.

Secondary: Percentage of Subjects Achieving Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Titers Greater Than or Equal to (>=) Lower Limit of Quantitation (LLOQ) 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Titers Greater Than or Equal to (>=) Lower Limit of Quantitation (LLOQ) 1 Month After the Infant Series

End point description:

Percentage of subjects achieving serotype-specific pneumococcal OPA titer >= LLOQ, along with the

corresponding 95% CIs for 13 pneumococcal serotypes (4, 6B, 9V, 14, 18C, 19F, 23F, 1, 3, 5, 6A, 7F and 19A) are presented. Exact 2-sided CI based on the observed proportion of subjects. The OPA LLOQ in titers for each serotype: 1 = 1:18; 3 = 1:12; 4 = 1:21; 5 = 1:29; 6A = 1:37; 6B = 1:43; 7F = 1:210; 9V = 1:345; 14 = 1:35; 18C = 1:31; 19A = 1:18; 19F = 1:48; 23F = 1:13. mITT infant immunogenicity population. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm respectively.

End point type	Secondary
End point timeframe:	
1 month after the infant series	

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46[120]	48[121]	44[122]	44[123]
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n = 37, 46, 42, 41, 61)	100 (90.5 to 100)	100 (92.3 to 100)	100 (91.6 to 100)	100 (91.4 to 100)
6B (n = 36, 45, 43, 40, 62)	94.4 (81.3 to 99.3)	88.9 (75.9 to 96.3)	88.4 (74.9 to 96.1)	92.5 (79.6 to 98.4)
9V (n = 37, 48, 42, 41, 65)	62.2 (44.8 to 77.5)	66.7 (51.6 to 79.6)	59.5 (43.3 to 74.4)	80.5 (65.1 to 91.2)
14 (n = 38, 48, 41, 41, 64)	89.5 (75.2 to 97.1)	97.9 (88.9 to 99.9)	100 (91.4 to 100)	97.6 (87.1 to 99.9)
18C (n = 37, 47, 41, 41, 62)	100 (90.5 to 100)	95.7 (85.5 to 99.5)	100 (91.4 to 100)	97.6 (87.1 to 99.9)
19F (n = 37, 46, 41, 42, 63)	97.3 (85.8 to 99.9)	87 (73.7 to 95.1)	90.2 (76.9 to 97.3)	92.9 (80.5 to 98.5)
23F (n = 38, 45, 42, 42, 63)	92.1 (78.6 to 98.3)	97.8 (88.2 to 99.9)	92.9 (80.5 to 98.5)	90.5 (77.4 to 97.3)
1 (n = 42, 42, 43, 44, 74)	47.6 (32 to 63.6)	42.9 (27.7 to 59)	30.2 (17.2 to 46.1)	29.5 (16.8 to 45.2)
3 (n = 41, 41, 39, 39, 69)	97.6 (87.1 to 99.9)	97.6 (87.1 to 99.9)	97.4 (86.5 to 99.9)	94.9 (82.7 to 99.4)
5 (n = 42, 43, 44, 42, 73)	92.9 (80.5 to 98.5)	90.7 (77.9 to 97.4)	86.4 (72.6 to 94.8)	92.9 (80.5 to 98.5)
6A (n = 46, 42, 39, 39, 76)	93.5 (82.1 to 98.6)	100 (91.6 to 100)	100 (91 to 100)	100 (91 to 100)
7F (n = 46, 42, 40, 39, 76)	100 (92.3 to 100)	100 (91.6 to 100)	100 (91.2 to 100)	97.4 (86.5 to 99.9)
19A (n = 42, 44, 41, 42, 74)	92.9 (80.5 to 98.5)	100 (92 to 100)	90.2 (76.9 to 97.3)	88.1 (74.4 to 96)

Notes:

[120] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[121] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[122] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[123] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	76[124]			

Units: percentage of subjects				
number (confidence interval 95%)				
4 (n = 37, 46, 42, 41, 61)	100 (94.1 to 100)			
6B (n = 36, 45, 43, 40, 62)	96.8 (88.8 to 99.6)			
9V (n = 37, 48, 42, 41, 65)	75.4 (63.1 to 85.2)			
14 (n = 38, 48, 41, 41, 64)	96.9 (89.2 to 99.6)			
18C (n = 37, 47, 41, 41, 62)	100 (94.2 to 100)			
19F (n = 37, 46, 41, 42, 63)	95.2 (86.7 to 99)			
23F (n = 38, 45, 42, 42, 63)	93.7 (84.5 to 98.2)			
1 (n = 42, 42, 43, 44, 74)	45.9 (34.3 to 57.9)			
3 (n = 41, 41, 39, 39, 69)	100 (94.8 to 100)			
5 (n = 42, 43, 44, 42, 73)	86.3 (76.2 to 93.2)			
6A (n = 46, 42, 39, 39, 76)	98.7 (92.9 to 100)			
7F (n = 46, 42, 40, 39, 76)	100 (95.3 to 100)			
19A (n = 42, 44, 41, 42, 74)	97.3 (90.6 to 99.7)			

Notes:

[124] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer (GMT) for Serotype-specific Pneumococcal Opsonophagocytic Activity (OPA) 1 Month After the Infant Series

End point title	Geometric Mean Titer (GMT) for Serotype-specific Pneumococcal Opsonophagocytic Activity (OPA) 1 Month After the Infant Series

End point description:

Antibody-mediated serum OPA against the 13 pneumococcal serotypes (4, 6B, 9V, 14, 18C, 19F, 23F, 1, 3, 5, 6A, 7F and 19A) was measured centrally using a pneumococcal OPA assay. Results were expressed as OPA titers. OPA titers were logarithmically transformed for analysis; geometric means calculated and expressed as geometric mean titers (GMTs). mITT infant immunogenicity population. Here ‘n’ signifies subjects with a determinate OPA titer to the given serotype for each arm respectively. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46[125]	48[126]	44[127]	44[128]
Units: titer				
geometric mean (confidence interval 95%)				
4 (n = 37, 46, 42, 41, 61)	1269 (961.2 to 1674.2)	1135 (885.2 to 1456.1)	1240 (955.9 to 1609.3)	1361 (1045.4 to 1771)
6B (n = 36, 45, 43, 40, 62)	794 (450.4 to 1399.6)	655 (394.6 to 1087.9)	470 (279.9 to 789.7)	663 (387.2 to 1135.1)
9V (n = 37, 48, 42, 41, 65)	120 (52.5 to 274.2)	166 (80.5 to 343.3)	93 (43 to 203)	285 (129.8 to 623.8)
14 (n = 38, 48, 41, 41, 64)	435 (277.2 to 683.5)	622 (416 to 928.6)	650 (420.7 to 1003)	991 (642.1 to 1530.9)
18C (n = 37, 47, 41, 41, 62)	1094 (777.8 to 1539.2)	853 (630 to 1154.3)	877 (634.1 to 1212.7)	1031 (745.8 to 1426.2)
19F (n = 37, 46, 41, 42, 63)	346 (219.7 to 545.4)	221 (146.8 to 331.9)	165 (106.8 to 253.4)	294 (191.8 to 450.2)
23F (n = 38, 45, 42, 42, 63)	342 (211.6 to 552.6)	441 (283.7 to 685.4)	332 (210 to 523.4)	321 (203.3 to 506.7)
1 (n = 42, 42, 43, 44, 74)	12 (8.7 to 17.7)	11 (7.5 to 15.4)	8 (5.5 to 11.2)	8 (5.4 to 10.9)
3 (n = 41, 41, 39, 39, 69)	72 (57.4 to 91.1)	76 (60.4 to 95.7)	56 (44.1 to 70.8)	62 (49.3 to 79.1)
5 (n = 42, 43, 44, 42, 73)	86 (59.7 to 122.7)	96 (67.4 to 137.3)	54 (37.7 to 76.2)	99 (69.1 to 142)
6A (n = 46, 42, 39, 39, 76)	1060 (784.5 to 1431.1)	1681 (1227.3 to 2302.3)	1228 (886 to 1701.9)	1281 (924 to 1775.1)
7F (n = 46, 42, 40, 39, 76)	1766 (1387 to 2247.7)	1907 (1481 to 2454.6)	1747 (1348.6 to 2263.3)	1584 (1218.8 to 2058.9)
19A (n = 42, 44, 41, 42, 74)	185 (127.8 to 268.3)	257 (178.5 to 368.5)	163 (112.3 to 237.9)	159 (110 to 230.9)

Notes:

[125] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[126] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[127] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[128] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	76[129]			
Units: titer				
geometric mean (confidence interval 95%)				
4 (n = 37, 46, 42, 41, 61)	1086 (874.9 to 1347.9)			
6B (n = 36, 45, 43, 40, 62)	748 (485.6 to 1152)			
9V (n = 37, 48, 42, 41, 65)	241 (129 to 448.7)			
14 (n = 38, 48, 41, 41, 64)	951 (671.6 to 1346.3)			
18C (n = 37, 47, 41, 41, 62)	1092 (838.9 to 1421.3)			

19F (n = 37, 46, 41, 42, 63)	279 (196.8 to 395)			
23F (n = 38, 45, 42, 42, 63)	366 (252.4 to 532.1)			
1 (n = 42, 42, 43, 44, 74)	12 (9 to 15.5)			
3 (n = 41, 41, 39, 39, 69)	87 (73.1 to 104.3)			
5 (n = 42, 43, 44, 42, 73)	76 (57.5 to 99.2)			
6A (n = 46, 42, 39, 39, 76)	1462 (1157.1 to 1847.1)			
7F (n = 46, 42, 40, 39, 76)	2125 (1761.6 to 2564.6)			
19A (n = 42, 44, 41, 42, 74)	240 (181.9 to 318)			

Notes:

[129] - "N"(Number of subjects analyzed) signifies those subjects who were evaluable for this measure.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7148 [130]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.66

Notes:

[130] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7907 [131]
Method	General linear model
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.45

Notes:

[131] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4765 [132]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.6

Notes:

[132] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 4: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5037 [133]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.76

Notes:

[133] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9414 [134]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	2.17

Notes:

[134] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7907 [135]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.71

Notes:

[135] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.29 [136]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1.23

Notes:

[136] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6B: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8826 [137]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.44
upper limit	1.77

Notes:

[137] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5823 [138]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	1.4

Notes:

[138] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [139]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	1.8

Notes:

[139] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2407 [140]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.14
upper limit	1.05

Notes:

[140] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 9V: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8826 [141]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	3.22

Notes:

[141] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0961 [142]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	0.81

Notes:

[142] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [143]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.11

Notes:

[143] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.29 [144]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	1.19

Notes:

[144] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 14: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group..

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8826 [145]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.82

Notes:

[145] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9925 [146]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.54

Notes:

[146] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [147]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.17

Notes:

[147] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3929 [148]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.22

Notes:

[148] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 18C: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8826 [149]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.43

Notes:

[149] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7433 [150]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.2

Notes:

[150] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [151]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.35

Notes:

[151] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2407 [152]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	1.03

Notes:

[152] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8826 [153]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.83

Notes:

[153] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9414 [154]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.71

Notes:

[154] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [155]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	2.14

Notes:

[155] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.738 [156]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.63

Notes:

[156] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 23F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8826 [157]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.58

Notes:

[157] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9414 [158]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.65

Notes:

[158] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7907 [159]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.43

Notes:

[159] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2407 [160]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.04

Notes:

[160] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.267 [161]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	1.02

Notes:

[161] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5823 [162]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.11

Notes:

[162] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [163]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.16

Notes:

[163] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0422 [164]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	0.86

Notes:

[164] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.267 [165]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.96

Notes:

[165] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8454 [166]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.78

Notes:

[166] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [167]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	2

Notes:

[167] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2824 [168]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.11

Notes:

[168] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 5: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5155 [169]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	2.06

Notes:

[169] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5823 [170]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.06

Notes:

[170] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [171]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.7

Notes:

[171] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4644 [172]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.25

Notes:

[172] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 6A: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8826 [173]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.31

Notes:

[173] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5823 [174]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.13

Notes:

[174] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636 [175]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.23

Notes:

[175] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3299 [176]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.13

Notes:

[176] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 7F: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.267 [177]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.03

Notes:

[177] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5823 [178]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.23

Notes:

[178] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7907 [179]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.69

Notes:

[179] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2742 [180]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.09

Notes:

[180] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Serotype 19A: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.267 [181]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	1.05

Notes:

[181] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Haemophilus Influenzae Type b (Hib) Polyribosylribitol Phosphate (PRP) Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Haemophilus Influenzae Type b (Hib) Polyribosylribitol Phosphate (PRP) Antibody 1 Month After the Infant Series

End point description:

Geometric LS mean concentrations (GMCs) and corresponding 2-sided 95% CIs were evaluated for Hib PRP antibody.mITT infant immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136[182]	146[183]	144[184]	139[185]
Units: mcg/mL				
geometric mean (confidence interval 95%)	0.54 (0.44 to 0.66)	0.59 (0.49 to 0.73)	0.49 (0.4 to 0.6)	0.51 (0.42 to 0.63)

Notes:

[182] - Subjects who were evaluable for this measure.

[183] - Subjects who were evaluable for this measure.

[184] - Subjects who were evaluable for this measure.

[185] - Subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	198[186]			
Units: mcg/mL				
geometric mean (confidence interval 95%)	0.58 (0.49 to 0.69)			

Notes:

[186] - Subjects who were evaluable for this measure.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.813 [187]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.22

Notes:

[187] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	344
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.845 [188]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.34

Notes:

[188] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	342
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.461 [189]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.11

Notes:

[189] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant

Number of subjects included in analysis	337
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.545 [190]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.16

Notes:

[190] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Pertussis Toxin (PT), Filamentous Hemagglutinin (FHA) and Pertactin (PRN) Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Pertussis Toxin (PT), Filamentous Hemagglutinin (FHA) and Pertactin (PRN) Antibody 1 Month After the Infant Series

End point description:

Geometric LS mean concentration (GMCs) were measured in Enzyme-linked Immunosorbent Assay (ELISA) units/mL (EU/mL) and corresponding 2-sided 95% CIs were evaluated for pertussis (pertussis toxin [PT], filamentous hemagglutinin [FHA] and pertactin [PRN]) antibodies. mITT infant immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132[191]	143[192]	141[193]	131[194]
Units: EU/mL				
geometric mean (confidence interval 95%)				
Pertussis PT	40.86 (36.49 to 45.76)	43.51 (39.02 to 48.51)	40.27 (36.09 to 44.93)	39.26 (35.04 to 43.98)
Pertussis FHA	46.29 (41.49 to 51.65)	40.65 (36.59 to 45.16)	41.32 (37.16 to 45.94)	35.55 (31.85 to 39.68)
Pertussis PRN	72.9 (63.26 to 84.01)	71.26 (62.18 to 81.66)	65.82 (57.38 to 75.5)	68.53 (59.44 to 79.02)

Notes:

[191] - Subjects who were evaluable for this measure.

[192] - Subjects who were evaluable for this measure.

[193] - Subjects who were evaluable for this measure.

[194] - Subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	193[195]			
Units: EU/mL				
geometric mean (confidence interval 95%)				
Pertussis PT	44.85 (40.84 to 49.25)			
Pertussis FHA	48.42 (44.22 to 53.01)			
Pertussis PRN	84.57 (75.21 to 95.09)			

Notes:

[195] - Subjects who were evaluable for this measure.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PT: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.712 [196]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.06

Notes:

[196] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PT: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant

Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.837 [197]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.12

Notes:

[197] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PT: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.357 [198]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.04

Notes:

[198] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PT: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.19 [199]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.88

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.01

Notes:

[199] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis FHA: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.813 [200]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.1

Notes:

[200] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis FHA: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.136 [201]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.96

Notes:

[201] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis FHA: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.104 [202]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.98

Notes:

[202] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis FHA: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [203]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.85

Notes:

[203] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PRN: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant

Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.712 [204]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.04

Notes:

[204] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PRN: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.206 [205]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.01

Notes:

[205] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PRN: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.066 [206]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.78

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.93

Notes:

[206] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PRN: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.085 [207]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.97

Notes:

[207] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Tetanus and Diphtheria Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Tetanus and Diphtheria Antibody 1 Month After the Infant Series

End point description:

Geometric LS mean concentration (GMCs) were measured in International Units/mL (IU/mL) and corresponding 2-sided 95% CIs were evaluated for tetanus and diphtheria antibodies. mITT infant immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132[208]	143[209]	141[210]	131[211]
Units: IU/mL				
geometric mean (confidence interval 95%)				
Tetanus	0.73 (0.65 to 0.83)	0.7 (0.62 to 0.79)	0.69 (0.61 to 0.77)	0.6 (0.53 to 0.68)
Diphtheria	0.62 (0.56 to 0.69)	0.68 (0.61 to 0.75)	0.61 (0.55 to 0.68)	0.65 (0.59 to 0.73)

Notes:

[208] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[209] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[210] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[211] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	193[212]			
Units: IU/mL				
geometric mean (confidence interval 95%)				
Tetanus	0.82 (0.74 to 0.9)			
Diphtheria	0.65 (0.6 to 0.72)			

Notes:

[212] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Tetanus: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.712 [213]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.06

Notes:

[213] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Tetanus: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.206 [214]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1

Notes:

[214] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Tetanus: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.104 [215]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.98

Notes:

[215] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Tetanus: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [216]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.87

Notes:

[216] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Diphtheria: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.813 [217]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.09

Notes:

[217] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Diphtheria: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.837 [218]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.19

Notes:

[218] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Diphtheria: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.534 [219]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.07

Notes:

[219] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Diphtheria: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.961 [220]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.15

Notes:

[220] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Hepatitis B Virus (HBV) Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Hepatitis B Virus (HBV) Antibody 1 Month After the Infant Series

End point description:

Geometric LS mean concentration (GMCs) were measured in milli international units/mL (mIU/mL) and corresponding 2-sided 95% CIs were evaluated for hepatitis B virus (HBV) antibody. mITT infant immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	105[221]	116[222]	120[223]	112[224]
Units: mIU/mL				
geometric mean (confidence interval 95%)	756.42 (589.71 to 970.26)	770.93 (608.34 to 976.98)	689.34 (546.12 to 870.11)	599.12 (470.78 to 762.43)

Notes:

[221] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[222] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[223] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[224] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	156[225]			
Units: mIU/mL				
geometric mean (confidence interval 95%)	733.29 (597.81 to 899.46)			

Notes:

[225] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant v 13vPnC + INFANRIX Hexa:Infant

Number of subjects included in analysis	261
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [226]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.42

Notes:

[226] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	272
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.837 [227]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.44

Notes:

[227] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	276
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.695 [228]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.94

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.28

Notes:

[228] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	268
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.408 [229]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.12

Notes:

[229] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Titer (GMT) for Antigen-specific Poliomyelitis Type 1, 2 and 3 Antibodies 1 Month After the Infant Series

End point title	Geometric Mean Titer (GMT) for Antigen-specific Poliomyelitis Type 1, 2 and 3 Antibodies 1 Month After the Infant Series

End point description:

Geometric LS mean concentrations (GMCs) were measured as titers and corresponding 2-sided 95% CIs were evaluated for poliomyelitis type 1, 2 and 3 antibodies. mITT infant immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	89[230]	105[231]	93[232]	84[233]
Units: titer				

geometric mean (confidence interval 95%)				
Poliomyelitis Type 1	68.11 (53.14 to 87.3)	66.59 (52.98 to 83.68)	67.43 (52.89 to 85.96)	70.66 (54.73 to 91.23)
Poliomyelitis Type 2	79.6 (61.54 to 102.95)	73.52 (58.01 to 93.16)	62.12 (48.3 to 79.9)	55.17 (42.33 to 71.89)
Poliomyelitis Type 3	246.22 (192.84 to 314.38)	184.03 (146.96 to 230.46)	257.92 (203.08 to 327.56)	218.85 (170.18 to 281.44)

Notes:

[230] - Subjects who were evaluable for this measure.

[231] - Subjects who were evaluable for this measure.

[232] - Subjects who were evaluable for this measure.

[233] - Subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	135[234]			
Units: titer				
geometric mean (confidence interval 95%)				
Poliomyelitis Type 1	72.02 (58.88 to 88.1)			
Poliomyelitis Type 2	67.37 (54.67 to 83.02)			
Poliomyelitis Type 3	231.02 (189.44 to 281.72)			

Notes:

[234] - Subjects who were evaluable for this measure.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant v 13vPnC + INFANRIX Hexa:Infant
Number of subjects included in analysis	224
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.813 [235]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.3

Notes:

[235] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	240
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.837 [236]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.25

Notes:

[236] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	228
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.695 [237]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.28

Notes:

[237] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.961 [238]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.36

Notes:

[238] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 2: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	224
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.808 [239]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.65

Notes:

[239] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 2: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	240
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.837 [240]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.09

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.5

Notes:

[240] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 2: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant
Number of subjects included in analysis	228
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.695 [241]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.28

Notes:

[241] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 2: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.408 [242]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.15

Notes:

[242] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant
Number of subjects included in analysis	224
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.813 [243]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.46

Notes:

[243] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant
Number of subjects included in analysis	240
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.343 [244]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.08

Notes:

[244] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant

Number of subjects included in analysis	228
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.695 [245]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.52

Notes:

[245] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Infant v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Number of subjects included in analysis	219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.925 [246]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.31

Notes:

[246] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Haemophilus Influenzae Type b (Hib) Polyribosylribitol Phosphate (PRP) Antibody 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Haemophilus Influenzae Type b (Hib) Polyribosylribitol Phosphate (PRP) Antibody 1 Month After the Toddler Dose

End point description:

Geometric LS mean concentration (GMCs) were measured in mcg/mL and corresponding 2-sided 95% CIs were evaluated for Hib PRP antibody. mITT toddler immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126[247]	135[248]	141[249]	138[250]
Units: mcg/mL				
geometric mean (confidence interval 95%)	9.65 (7.74 to 12.03)	9.35 (7.55 to 11.57)	8.25 (6.69 to 10.16)	7.84 (6.35 to 9.68)

Notes:

[247] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[248] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[249] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[250] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

End point values	13vPnC + INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	202[251]			
Units: mcg/mL				
geometric mean (confidence interval 95%)	8.96 (7.53 to 10.67)			

Notes:

[251] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler v 13vPnC + INFANRIX Hexa:Toddler
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91 [252]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.43

Notes:

[252] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	337
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [253]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.37

Notes:

[253] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	343
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.868 [254]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.21

Notes:

[254] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler

Number of subjects included in analysis	340
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.914 [255]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.15

Notes:

[255] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Pertussis Toxin (PT), Filamentous Hemagglutinin (FHA) and Pertactin (PRN) Antibodies 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Pertussis Toxin (PT), Filamentous Hemagglutinin (FHA) and Pertactin (PRN) Antibodies 1 Month After the Toddler Dose

End point description:

Geometric LS mean concentration (GMCs) were measured in EU/mL and corresponding 2-sided 95% CIs were evaluated for pertussis (pertussis toxin [PT], filamentous hemagglutinin [FHA] and pertactin [PRN]) antibodies. mITT toddler immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123[256]	137[257]	141[258]	136[259]
Units: EU/mL				
geometric mean (confidence interval 95%)				
Pertussis PT	77.43 (68.12 to 88.02)	76.93 (68.13 to 86.87)	73.72 (65.4 to 83.1)	73.38 (64.96 to 82.9)
Pertussis FHA	115.55 (104.32 to 128)	117.87 (106.98 to 129.87)	123.56 (112.3 to 135.95)	108.11 (98.09 to 119.16)
Pertussis PRN	158.28 (136.3 to 183.81)	156.98 (136.24 to 180.87)	160.96 (139.98 to 185.08)	158.71 (137.67 to 182.97)

Notes:

[256] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[257] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[258] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[259] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

End point values	13vPnC + INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	199[260]			
Units: EU/mL				
geometric mean (confidence interval 95%)				
Pertussis PT	74.01 (66.91 to 81.86)			
Pertussis FHA	117.01 (107.97 to 126.81)			
Pertussis PRN	172.8 (153.64 to 194.36)			

Notes:

[260] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PT: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler v 13vPnC + INFANRIX Hexa:Toddler
Number of subjects included in analysis	322
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91 [261]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.23

Notes:

[261] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PT: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler

Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [262]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.22

Notes:

[262] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PT: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	340
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.961 [263]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.16

Notes:

[263] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PT: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.916 [264]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.99

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.16

Notes:

[264] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis FHA: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	322
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91 [265]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.12

Notes:

[265] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis FHA: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler v 13vPnC + INFANRIX Hexa:Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.909 [266]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.14

Notes:

[266] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis FHA: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	340
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.868 [267]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.2

Notes:

[267] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis FHA: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.914 [268]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.05

Notes:

[268] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PRN: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler

Number of subjects included in analysis	322
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91 [269]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.11

Notes:

[269] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PRN: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [270]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.09

Notes:

[270] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PRN: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	340
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.868 [271]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.12

Notes:

[271] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Pertussis PRN: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.914 [272]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.1

Notes:

[272] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Tetanus and Diphtheria Antibodies 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Tetanus and Diphtheria Antibodies 1 Month After the Toddler Dose

End point description:

Geometric LS mean concentration (GMCs) were measured in IU/mL and corresponding 2-sided 95% CIs were evaluated for tetanus and diphtheria antibodies. mITT toddler immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123[273]	137[274]	141[275]	136[276]
Units: IU/mL				
geometric mean (confidence interval 95%)				
Tetanus	2.54 (2.28 to 2.83)	2.5 (2.26 to 2.77)	2.6 (2.35 to 2.88)	2.29 (2.07 to 2.54)
Diphtheria	1.64 (1.49 to 1.8)	1.94 (1.77 to 2.12)	1.69 (1.54 to 1.84)	1.87 (1.71 to 2.04)

Notes:

[273] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[274] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen.

[275] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen

[276] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen

End point values	13vPnC + INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	199[277]			
Units: IU/mL				
geometric mean (confidence interval 95%)				
Tetanus	2.66 (2.44 to 2.89)			
Diphtheria	1.9 (1.77 to 2.05)			

Notes:

[277] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Tetanus: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	322
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91 [278]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.1

Notes:

[278] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Tetanus: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [279]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.07

Notes:

[279] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Tetanus: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	340
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.939 [280]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.12

Notes:

[280] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Tetanus: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.279 [281]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.98

Notes:

[281] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Diphtheria: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	322
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.149 [282]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	0.97

Notes:

[282] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Diphtheria: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [283]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.14

Notes:

[283] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Diphtheria: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	340
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.394 [284]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	0.99

Notes:

[284] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Diphtheria: Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.916 [285]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.1

Notes:

[285] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Hepatitis B Virus (HBV) Antibody 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Hepatitis B Virus (HBV) Antibody 1 Month After the Toddler Dose

End point description:

Geometric LS mean concentration (GMCs) were measured in mIU/mL and corresponding 2-sided 95% CIs were evaluated for hepatitis B virus (HBV) antibody. mITT toddler immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	119[286]	131[287]	133[288]	133[289]
Units: mIU/mL				
geometric mean (confidence interval 95%)	4868.61 (3750.57 to 6319.94)	4148.04 (3234.82 to 5319.08)	4250.41 (3320.88 to 5440.13)	4263.28 (3330.93 to 5456.6)

Notes:

[286] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen

[287] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen

[288] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen

[289] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen

End point values	13vPnC + INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	191[290]			
Units: mIU/mL				
geometric mean (confidence interval 95%)	3866.37 (3146.78 to 4750.52)			

Notes:

[290] - Subjects with a determinate antibody concentration to the given concomitant vaccine antigen

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler v 13vPnC + INFANRIX Hexa:Toddler

Number of subjects included in analysis	310
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.869 [291]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.76

Notes:

[291] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	322
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [292]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.48

Notes:

[292] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.868 [293]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.52

Notes:

[293] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Ratio of GMCs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.916 [294]
Method	General Linear Model
Parameter estimate	GMC Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.52

Notes:

[294] - P-values were adjusted using false discovery rate procedure.

Secondary: Geometric Mean Titer (GMT) for Antigen-specific Poliomyelitis Type 1, 2 and 3 Antibodies 1 Month After the Toddler Dose

End point title	Geometric Mean Titer (GMT) for Antigen-specific Poliomyelitis Type 1, 2 and 3 Antibodies 1 Month After the Toddler Dose

End point description:

Geometric LS mean concentration (GMCs) were measured as titers and corresponding 2-sided 95% CIs were evaluated for poliomyelitis type 1, 2 and 3 antibodies. mITT toddler immunogenicity population. Paracetamol and Ibuprofen have been abbreviated as PCM and IBF, respectively in the statistical analysis titles.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123[295]	133[296]	141[297]	136[298]
Units: titer				

geometric mean (confidence interval 95%)				
Poliomyelitis Type 1	399.56 (332.13 to 480.68)	426.63 (357.15 to 509.62)	443.97 (373.58 to 527.63)	415.45 (348.48 to 495.29)
Poliomyelitis Type 2	613.18 (515.3 to 729.65)	586.3 (496.01 to 693.03)	587.56 (499.47 to 691.18)	605.78 (513.44 to 714.73)
Poliomyelitis Type 3	1205.8 (1001.18 to 1452.24)	1045.57 (874.35 to 1250.32)	1210.29 (1017.32 to 1439.87)	1187.11 (994.68 to 1416.76)

Notes:

[295] - Subjects who were evaluable for this measure.

[296] - Subjects who were evaluable for this measure.

[297] - Subjects who were evaluable for this measure.

[298] - Subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	201[299]			
Units: titer				
geometric mean (confidence interval 95%)				
Poliomyelitis Type 1	406.37 (351.67 to 469.59)			
Poliomyelitis Type 2	621.07 (542.07 to 711.57)			
Poliomyelitis Type 3	1237.86 (1070.27 to 1431.7)			

Notes:

[299] - Subjects who were evaluable for this measure.

Statistical analyses

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler v 13vPnC + INFANRIX Hexa:Toddler
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91 [300]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.24

Notes:

[300] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [301]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.32

Notes:

[301] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	342
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.868 [302]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.37

Notes:

[302] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 1: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	337
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.916 [303]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.28

Notes:

[303] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 2: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91 [304]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.23

Notes:

[304] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 2: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler

Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [305]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.17

Notes:

[305] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 2: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	342
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.868 [306]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.17

Notes:

[306] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 2: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	337
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.916 [307]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.21

Notes:

[307] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91 [308]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.23

Notes:

[308] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Twice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen twice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [309]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.06

Notes:

[309] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+PCM Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Paracetamol thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler
Number of subjects included in analysis	342
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.939 [310]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.23

Notes:

[310] - P-values were adjusted using false discovery rate procedure.

Statistical analysis title	13vPnC+INFANRIX+IBF Thrice vs 13vPnC+INFANRIX

Statistical analysis description:

Poliomyelitis Type 3: Ratio of GMTs along with 2-sided 95% CI were back transformed from the difference of the LS mean of 13vPnC + INFANRIX hexa + Ibuprofen thrice daily group minus the LS mean of 13vPnC + INFANRIX hexa group.

Comparison groups	13vPnC + INFANRIX Hexa:Toddler v 13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Number of subjects included in analysis	337
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.916 [311]
Method	General Linear Model
Parameter estimate	GMT Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.21

Notes:

[311] - P-values were adjusted using false discovery rate procedure.

Secondary: Percentage of Subjects Achieving Pre-specified Criteria for the Concomitant Antigens Contained in INFANRIX Hexa 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Pre-specified Criteria for the Concomitant Antigens Contained in INFANRIX Hexa 1 Month After the Infant Series

End point description:

Percentage of subjects achieving pre-specified criteria for concomitant antigens contained in INFANRIX hexa (Hib polyribosylribitol phosphate [PRP] >=0.15 mcg/mL; Hib PRP >=1 mcg/mL; Pertussis PT >=14.6 EU/mL, FHA >=16.1 EU/mL, PRN >=24.0 EU/mL; Tetanus >=0.1 IU/mL; Diphtheria >=0.1

IU/mL; HBV >=10 mIU/mL; Poliomyelitis Type 1, 2, 3 >=1:8 titer) along with the corresponding 95% CIs were presented. Exact 2-sided CI based on the observed proportion of subjects. Pre-specified criteria for pertussis was the level that 95% of the subjects achieved in 13vPnC + INFANRIX hexa group. mITT infant immunogenicity population. Here 'n' signifies subjects with a determinate antibody concentration or titer to the given concomitant vaccine antigen for each arm respectively.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136[312]	146[313]	144[314]	139[315]
Units: percentage of subjects				
number (confidence interval 95%)				
Hib PRP >=0.15 mcg/mL (n= 136, 146, 144, 139, 198)	87.5 (80.7 to 92.5)	84.2 (77.3 to 89.7)	86.1 (79.4 to 91.3)	85.6 (78.7 to 91)
Hib PRP >=1 mcg/mL (n = 136, 146, 144, 139, 198)	33.8 (25.9 to 42.4)	37 (29.2 to 45.4)	27.1 (20 to 35.1)	28.1 (20.8 to 36.3)
Pertussis PT >=14.6 EU/mL (n= 132,143,141,131,193)	93.2 (87.5 to 96.8)	97.2 (93 to 99.2)	91.5 (85.6 to 95.5)	90.8 (84.5 to 95.2)
Pertussis FHA >=16.1 EU/mL (n=132,143,141,131,193)	96.2 (91.4 to 98.8)	92.3 (86.7 to 96.1)	93.6 (88.2 to 97)	88.5 (81.8 to 93.4)
Pertussis PRN >=24.0 EU/mL (n=132,143,141,131,193)	90.9 (84.7 to 95.2)	87.4 (80.8 to 92.4)	88.7 (82.2 to 93.4)	89.3 (82.7 to 94)
Tetanus >=0.1 IU/mL (n = 132,143,141,131,193)	100 (97.2 to 100)	100 (97.5 to 100)	100 (97.4 to 100)	98.5 (94.6 to 99.8)
Diphtheria >=0.1 IU/mL (n = 132,143,141,131,193)	100 (97.2 to 100)	98.6 (95 to 99.8)	99.3 (96.1 to 100)	97.7 (93.5 to 99.5)
HBV >= 10mIU/mL (n = 105,116,120,112,156)	100 (96.5 to 100)	99.1 (95.3 to 100)	99.2 (95.4 to 100)	99.1 (95.1 to 100)
PoliomyelitisType1 >=1:8titer (n=89,105,93,84,135)	97.8 (92.1 to 99.7)	98.1 (93.3 to 99.8)	97.8 (92.4 to 99.7)	100 (95.7 to 100)
PoliomyelitisType2 >=1:8titer (n=89,105,93,84,135)	95.5 (88.9 to 98.8)	98.1 (93.3 to 99.8)	95.7 (89.4 to 98.8)	96.4 (89.9 to 99.3)
PoliomyelitisType3 >=1:8titer (n=89,105,93,84,135)	100 (95.9 to 100)	100 (96.5 to 100)	98.9 (94.2 to 100)	98.8 (93.5 to 100)

Notes:

[312] - Subjects who were evaluable for this measure.

[313] - Subjects who were evaluable for this measure.

[314] - Subjects who were evaluable for this measure.

[315] - Subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	198[316]			
Units: percentage of subjects				
number (confidence interval 95%)				
Hib PRP >=0.15 mcg/mL (n= 136, 146, 144, 139, 198)	87.9 (82.5 to 92.1)			

Hib PRP >=1 mcg/mL (n = 136, 146, 144, 139, 198)	33.8 (27.3 to 40.9)			
Pertussis PT >=14.6 EU/mL (n= 132,143,141,131,193)	95.3 (91.3 to 97.8)			
Pertussis FHA >=16.1 EU/mL (n=132,143,141,131,193)	95.3 (91.3 to 97.8)			
Pertussis PRN >=24.0 EU/mL (n=132,143,141,131,193)	95.3 (91.3 to 97.8)			
Tetanus >=0.1 IU/mL (n = 132,143,141,131,193)	99.5 (97.1 to 100)			
Diphtheria >=0.1 IU/mL (n = 132,143,141,131,193)	99.5 (97.1 to 100)			
HBV >= 10mIU/mL (n = 105,116,120,112,156)	98.7 (95.4 to 99.8)			
PoliomyelitisType1 >=1:8titer (n=89,105,93,84,135)	99.3 (95.9 to 100)			
PoliomyelitisType2 >=1:8titer (n=89,105,93,84,135)	95.6 (90.6 to 98.4)			
PoliomyelitisType3 >=1:8titer (n=89,105,93,84,135)	99.3 (95.9 to 100)			

Notes:

[316] - Subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Pre-specified Criteria for the Concomitant Antigens Contained in INFANRIX Hexa 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving Pre-specified Criteria for the Concomitant Antigens Contained in INFANRIX Hexa 1 Month After the Toddler Dose

End point description:

Percentage of subjects achieving pre-specified criteria for concomitant antigens contained in INFANRIX hexa (Hib polyribosylribitol phosphate [PRP] >=0.15 mcg/mL; Hib PRP >=1 mcg/mL; Pertussis PT >=14.8 EU/mL, FHA >=46.5 EU/mL, PRN >=43.5 EU/mL; Tetanus >=0.1 IU/mL; Diphtheria >=0.1 IU/mL; HBV >=10 mIU/mL; Poliomyelitis Type 1, 2, 3 >=1:8 titer) along with the corresponding 95% CIs were presented. Exact 2-sided CI based on the observed proportion of subjects. Pre-specified criteria for pertussis was the level that 95% of the subjects achieved in 13vPnC + INFANRIX hexa group. mITT toddler immunogenicity population. Here 'n' signifies subjects with a determinate antibody concentration or titer to the given concomitant vaccine antigen for each arm respectively.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126[317]	137[318]	141[319]	138[320]
Units: percentage of subjects				
number (confidence interval 95%)				
Hib PRP >=0.15 mcg/mL (n= 126, 135, 141, 138, 202)	100 (97.1 to 100)	99.3 (95.9 to 100)	100 (97.4 to 100)	100 (97.4 to 100)

Hib PRP >=1 mcg/mL (n = 126, 135, 141, 138, 202)	95.2 (89.9 to 98.2)	96.3 (91.6 to 98.8)	95.7 (91 to 98.4)	95.7 (90.8 to 98.4)
Pertussis PT >=14.8 EU/mL (n= 123,137,141,136,199)	97.6 (93 to 99.5)	99.3 (96 to 100)	98.6 (95 to 99.8)	100 (97.3 to 100)
Pertussis FHA >=46.5 EU/mL (n=123,137,141,136,199)	91.1 (84.6 to 95.5)	94.9 (89.8 to 97.9)	93.6 (88.2 to 97)	92.6 (86.9 to 96.4)
Pertussis PRN >=43.5 EU/mL (n=123,137,141,136,199)	91.9 (85.6 to 96)	94.9 (89.8 to 97.9)	94.3 (89.1 to 97.5)	94.1 (88.7 to 97.4)
Tetanus >=0.1 IU/mL (n = 123,137,141,136,199)	100 (97 to 100)	100 (97.3 to 100)	100 (97.4 to 100)	100 (97.3 to 100)
Diphtheria >=0.1 IU/mL (n = 123,137,141,136,199)	100 (97 to 100)	100 (97.3 to 100)	100 (97.4 to 100)	100 (97.3 to 100)
HBV >= 10 mIU/mL (n = 119,131,133,133,191)	100 (96.9 to 100)	98.5 (94.6 to 99.8)	100 (97.3 to 100)	100 (97.3 to 100)
Poliomyelitis 1 >=1:8titer (n=123,133,141,136,201)	99.2 (95.6 to 100)	100 (97.3 to 100)	100 (97.4 to 100)	100 (97.3 to 100)
Poliomyelitis 2 >=1:8titer (n=123,133,141,136,201)	100 (97 to 100)	100 (97.3 to 100)	100 (97.4 to 100)	100 (97.3 to 100)
Poliomyelitis 3 >=1:8titer (n=123,133,141,136,201)	100 (97 to 100)	100 (97.3 to 100)	100 (97.4 to 100)	100 (97.3 to 100)

Notes:

[317] - Subjects who were evaluable for this measure.

[318] - Subjects who were evaluable for this measure.

[319] - Subjects who were evaluable for this measure.

[320] - Subjects who were evaluable for this measure.

End point values	13vPnC + INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	202[321]			
Units: percentage of subjects				
number (confidence interval 95%)				
Hib PRP >=0.15 mcg/mL (n= 126, 135, 141, 138, 202)	100 (98.2 to 100)			
Hib PRP >=1 mcg/mL (n = 126, 135, 141, 138, 202)	95 (91.1 to 97.6)			
Pertussis PT >=14.8 EU/mL (n= 123,137,141,136,199)	95.5 (91.6 to 97.9)			
Pertussis FHA >=46.5 EU/mL (n=123,137,141,136,199)	95.5 (91.6 to 97.9)			
Pertussis PRN >=43.5 EU/mL (n=123,137,141,136,199)	95.5 (91.6 to 97.9)			
Tetanus >=0.1 IU/mL (n = 123,137,141,136,199)	100 (98.2 to 100)			
Diphtheria >=0.1 IU/mL (n = 123,137,141,136,199)	100 (98.2 to 100)			
HBV >= 10 mIU/mL (n = 119,131,133,133,191)	99.5 (97.1 to 100)			
Poliomyelitis 1 >=1:8titer (n=123,133,141,136,201)	99.5 (97.3 to 100)			
Poliomyelitis 2 >=1:8titer (n=123,133,141,136,201)	100 (98.2 to 100)			
Poliomyelitis 3 >=1:8titer (n=123,133,141,136,201)	100 (98.2 to 100)			

Notes:

[321] - Subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reporting Fever Within 4 Days: Infant Series Dose 1

End point title	Percentage of Subjects Reporting Fever Within 4 Days: Infant Series Dose 1

End point description:

Subjects' core (rectal) temperature was collected for 4 days after each vaccination using an electronic diary. Subjects' temperature was collected at 6 to 8 hours after vaccination, 6 to 8 hours following that and coincidentally with antipyretic administration for groups receiving antipyretics. Temperature was recorded at bedtime daily for 3 following days (Day 2 to Day 4) and at any time during the 3 days when fever was suspected. The highest temperature for each day was recorded in the e-diary. Incidences of fever were presented in following categories: >=38 but <=39 degree Celsius (degree C), greater than (>) 39 but <=40 degree C and >40 degree C.Safety analysis set Dose 1: subjects who received Dose 1 of 13vPnC/INFANRIX hexa in infant series, had Adverse Event (AE) or temperature data. Here 'n' signifies subjects reporting yes for >=1 day or no for all days for specified event for each arm respectively.

End point type	Secondary

End point timeframe:

Within 4 days after infant series Dose 1

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	149[322]	157[323]	147[324]	155[325]
Units: percentage of subjects				
number (not applicable)				
Fever >=38, <=39 degree C (n= 149,157,147,155,187)	32.9	45.2	18.4	34.2
Fever >39, <=40 degree C (n = 138,145,137,146,170)	1.4	1.4	0.7	0.7
Fever >40 degree C (n = 138,145,137,146,170)	0	0	0	0

Notes:

[322] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[323] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[324] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[325] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	187[326]			
Units: percentage of subjects				
number (not applicable)				
Fever >=38, <=39 degree C (n= 149,157,147,155,187)	41.7			
Fever >39, <=40 degree C (n = 138,145,137,146,170)	1.2			

Fever >40 degree C (n = 138,145,137,146,170)	0			

Notes:

[326] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reporting Fever Within 4 Days: Infant Series Dose 2

End point title	Percentage of Subjects Reporting Fever Within 4 Days: Infant Series Dose 2

End point description:

Subjects' rectal temperature was collected for 4 days after each vaccination using an electronic diary. Subjects' temperature was collected at 6 to 8 hours after vaccination, 6 to 8 hours following that and coincidentally with antipyretic administration for groups receiving antipyretics. Temperature was recorded at bedtime daily for 3 following days (Day 2 to Day 4) and at any time during the 3 days when fever was suspected. The highest temperature for each day was recorded in the e-diary. Incidences of fever were presented in following categories: >=38 but <=39 degree C, >39 but <=40 degree C and >40 degree C. Safety analysis set Dose 2: subjects who received Dose 2 of 13vPnC/INFANRIX hexa in infant series and had AE or temperature data available. Here, 'n' signifies subjects reporting yes for >=1 day or no for all days for specified event for each arm respectively.

End point type	Secondary

End point timeframe:

Within 4 days after infant series Dose 2

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	141[327]	152[328]	140[329]	159[330]
Units: percentage of subjects				
number (not applicable)				
Fever >=38, <=39 degree C (n= 141,152,140,159,181)	26.2	42.8	21.4	44
Fever >39, <=40 degree C (n = 133,140,134,145,164)	1.5	0.7	1.5	1.4
Fever >40 degree C (n = 131,140,133,144,164)	0	0	0	0

Notes:

[327] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[328] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[329] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[330] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	181[331]			

Units: percentage of subjects				
number (not applicable)				
Fever >=38, <=39 degree C (n= 141,152,140,159,181)	39.8			
Fever >39, <=40 degree C (n = 133,140,134,145,164)	3.7			
Fever >40 degree C (n = 131,140,133,144,164)	0			

Notes:

[331] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reporting Fever Within 4 Days: Infant Series Dose 3

End point title	Percentage of Subjects Reporting Fever Within 4 Days: Infant Series Dose 3

End point description:

Subjects' rectal temperature was collected for 4 days after each vaccination using an electronic diary. Subjects' temperature was collected at 6 to 8 hours after vaccination, 6 to 8 hours following that and coincidentally with antipyretic administration for groups receiving antipyretics. Temperature was recorded at bedtime daily for 3 following days (Day 2 to Day 4) and at any time during the 3 days when fever was suspected. The highest temperature for each day was recorded in the e-diary. Incidences of fever were presented in following categories: >=38 but <=39 degree C, >39 but <=40 degree C and >40 degree C. Report of fever >40 degrees C after 13vPnC Infant Series Dose 3 was confirmed as data entry error.Safety analysis set Dose 3: subjects who received Dose 3 of 13vPnC/INFANRIX hexa in infant series and had AE or temperature data available.Here,'n' signifies subjects reporting yes for >=1 day or no for all days for specified event for each arm respectively.

End point type	Secondary

End point timeframe:

Within 4 days after infant series Dose 3

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136[332]	146[333]	135[334]	141[335]
Units: percentage of subjects				
number (not applicable)				
Fever >=38, <=39 degree C (n= 136,146,135,141,175)	22.1	30.8	17	33.3
Fever >39, <=40 degree C (n = 129,137,125,136,167)	1.6	2.9	0.8	1.5
Fever >40 degree C (n = 128,136,126,135,166)	0	0	0.8	0

Notes:

[332] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[333] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[334] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

[335] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	175[336]			
Units: percentage of subjects				
number (not applicable)				
Fever >=38, <=39 degree C (n= 136,146,135,141,175)	29.7			
Fever >39, <=40 degree C (n = 129,137,125,136,167)	1.8			
Fever >40 degree C (n = 128,136,126,135,166)	0			

Notes:

[336] - Subjects reported yes for greater than or equal to (>=) 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reporting Fever Within 4 Days: Toddler Dose

End point title	Percentage of Subjects Reporting Fever Within 4 Days: Toddler Dose

End point description:

Subjects' rectal temperature was collected for 4 days after each vaccination using an electronic diary. Subjects' temperature was collected at 6 to 8 hours after vaccination, 6 to 8 hours following that and coincidentally with antipyretic administration for groups receiving antipyretics. Temperature was recorded at bedtime daily for 3 following days (Day 2 to Day 4) and at any time during the 3 days when fever was suspected. The highest temperature for each day was recorded in the e-diary. Incidences of fever were presented in following categories: >=38 but <=39 degree C, >39 but <=40 degree C and >40 degree C.Safety analysis set toddler dose: subjects who receive toddler dose of 13vPnC or INFANRIX hexa and had AE or temperature data available.Here,'n' signifies subjects reporting yes for >=1 day or no for all days for specified event for each arm, respectively.

End point type	Secondary

End point timeframe:

Within 4 days after toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	133[337]	140[338]	134[339]	144[340]
Units: percentage of subjects				
number (not applicable)				
Fever >=38, <=39 degree C (n= 133,140,134,144,162)	31.6	37.1	37.3	50
Fever >39, <=40 degree C (n = 128,127,118,123,150)	5.5	7.1	4.2	5.7

Fever >40 degree C (n = 123,125,117,122,150)	0	0	0	0

Notes:

[337] - Subjects reported yes for greater than or is equal to (>=) 1 day or no for all days.

[338] - Subjects reported yes for greater than or is equal to (>=) 1 day or no for all days.

[339] - Subjects reported yes for greater than or is equal to (>=) 1 day or no for all days.

[340] - Subjects reported yes for greater than or is equal to (>=) 1 day or no for all days.

End point values	13vPnC + INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	162[341]			
Units: percentage of subjects				
number (not applicable)				
Fever >=38, <=39 degree C (n= 133,140,134,144,162)	30.2			
Fever >39, <=40 degree C (n = 128,127,118,123,150)	2			
Fever >40 degree C (n = 123,125,117,122,150)	0			

Notes:

[341] - Subjects reported yes for greater than or is equal to (>=) 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Non-Serious Adverse Events (AEs) and Serious Adverse Events (SAEs): Infant Series

End point title	Number of Subjects With Non-Serious Adverse Events (AEs) and Serious Adverse Events (SAEs): Infant Series

End point description:

An AE was any untoward medical occurrence in a subject who received vaccine without regard to possibility of causal relationship. SAE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial/prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent events for infant series were events between infant series Dose 1 and up to 1 month (28 to 42 days) after infant series that were absent before treatment or that worsened relative to pre-treatment state. Reported non-SAEs included AEs other than SAEs collected using electronic diary (fever, systematic assessment) and events spontaneously collected on case report form at each visit (non-systematic assessment).Safety analysis set Dose 1 included all subjects who receive Dose 1 of 13vPnC or INFANRIX hexa in infant series and had AE or temperature data available.

End point type	Secondary

End point timeframe:

Baseline up to 1 Month (28 to 42 days) after infant series.

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Infant	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Infant	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Infant	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Infant
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	173	176	172	177

Units: subjects				
number (not applicable)				
Non-SAEs	57	71	67	72
SAEs	7	3	11	8

End point values	13vPnC + INFANRIX Hexa:Infant			
Subject group type	Reporting group			
Number of subjects analysed	210			
Units: subjects				
number (not applicable)				
Non-SAEs	80			
SAEs	10			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Non-Serious Adverse Events (AEs) and Serious Adverse Events (SAEs): After the Infant Series

End point title	Number of Subjects With Non-Serious Adverse Events (AEs) and Serious Adverse Events (SAEs): After the Infant Series

End point description:

An AE was any untoward medical occurrence in a subject who received vaccine without regard to possibility of causal relationship. SAE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial/prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent events after the infant series were events between 1 month (28 to 42 days) after infant series to toddler dose that were absent before treatment or that worsened relative to pre-treatment state. Reported non-SAEs included AEs other than SAEs spontaneously collected on case report form (non-systematic assessment). Safety analysis set Dose 3 included all subjects who receive Dose 3 of 13vPnC or INFANRIX hexa in infant series and had AE or temperature data available.

End point type	Secondary

End point timeframe:

1 Month (28 to 42 days) after infant series Dose 3 up to toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	170	174	172	176
Units: subjects				
number (not applicable)				
Non-SAEs	3	6	3	4
SAEs	6	14	10	11

End point values	13vPnC + INFANRIX Hexa			
Subject group type	Subject analysis set			
Number of subjects analysed	210			
Units: subjects				
number (not applicable)				
Non-SAEs	8			
SAEs	9			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Non-Serious Adverse Events (AEs) and Serious Adverse Events (SAEs): Toddler Dose

End point title	Number of Subjects With Non-Serious Adverse Events (AEs) and Serious Adverse Events (SAEs): Toddler Dose

End point description:

An AE was any untoward medical occurrence in a subject who received vaccine without regard to possibility of causal relationship. SAE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial/prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent events for toddler dose were events between toddler dose and up to 1 month (28 to 42 days) after toddler dose that were absent before treatment or that worsened relative to pre-treatment state. Reported non-SAEs included AEs other than SAEs collected using electronic diary (fever, systematic assessment) and events spontaneously collected on case report form at each visit (non-systematic assessment).Safety analysis set toddler dose included all subjects who receive toddler dose of 13vPnC or INFANRIX hexa and had AE or temperature data available.

End point type	Secondary

End point timeframe:

Toddler dose up to 1 Month (28 to 42 days) after toddler dose

End point values	13vPnC + INFANRIX Hexa + Paracetamol Twice Daily: Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily:Toddler	13vPnC + INFANRIX Hexa + Paracetamol Thrice Daily:Toddler	13vPnC + INFANRIX Hexa + Ibuprofen Thrice Daily:Toddler
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	169	173	170	175
Units: subjects				
number (not applicable)				
Non-SAEs	47	57	52	76
SAEs	3	2	1	1

End point values	13vPnC + INFANRIX Hexa:Toddler			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: subjects				
number (not applicable)				
Non-SAEs	50			
SAEs	1			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

AEs/SAEs: recorded from signing of informed consent form to completion of study. Subjects recorded pre-specified AEs in electronic diary: fever (up to 4 days after each vaccine dose).

Adverse event reporting additional description:

Safety population: subjects who received at least 1 dose of study vaccine. SAEs and AEs were grouped by system organ class and summarized. AEs included AEs collected in electronic diary (fever, systematic assessment) and events collected on case report form at each visit (nonsystematic assessment).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	13vPnC+ INFANRIX Hexa +Paracetamol Twice Daily -Infant Series

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series, along with paracetamol suspension 15 mg/kg orally at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol, assessed from Infant series Dose 1 through the blood draw 28 to 42 days post infant series.

Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily -Infant Series

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart, along with ibuprofen suspension 10 mg/kg orally at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen, assessed from Infant series Dose 1 through the blood draw 28 to 42 days post infant series.

Reporting group title	13vPnC+INFANRIX Hexa+Paracetamol Thrice Daily -Infant Series

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart, along with paracetamol suspension 15 mg/kg orally immediately after each vaccination, 6 to 8 hours after each vaccination and 6 to 8 hours after last dose of paracetamol, assessed from Infant series Dose 1 through the blood draw 28 to 42 days post infant series.

Reporting group title	13vPnC+ INFANRIX Hexa+ Ibuprofen Thrice Daily -Infant Series

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart, along with ibuprofen suspension 10 mg/kg orally immediately after each vaccination, 6 to 8 hours after each vaccination and 6 to 8 hours after last dose of ibuprofen, assessed from Infant series Dose 1 through the blood draw 28 to 42 days post infant series.

Reporting group title	13vPnC + INFANRIX Hexa - Infant Series

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart, assessed from Infant series Dose 1 through the blood draw 28 to 42 days post infant series (Inf Ser).

Reporting group title	13vPnC +INFANRIX Hexa +Paracetamol Twice Daily -After Inf Ser

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series (Inf Ser), along with paracetamol suspension 15 mg/kg orally at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol, assessed after the infant series blood draw up to toddler dose.

Reporting group title	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily -After Inf Ser

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series (Inf Ser), along with ibuprofen suspension 10 mg/kg orally at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen, assessed after the infant series blood draw up to toddler dose.

Reporting group title	13vPnC+INFANRIX Hexa +Paracetamol Thrice Daily -After Inf Ser

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series (Inf Ser), along with paracetamol suspension 15 mg/kg orally immediately after each vaccination, 6 to 8 hours after each vaccination and 6 to 8 hours after last dose of paracetamol, assessed after the infant series blood draw up to toddler dose.

Reporting group title	13vPnC +INFANRIX Hexa +Ibuprofen Thrice Daily -After Inf Ser

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series (Inf Ser), along with ibuprofen suspension 10 mg/kg orally immediately after each vaccination, 6 to 8 hours after each vaccination and 6 to 8 hours after last dose of ibuprofen, assessed after the infant series blood draw up to toddler dose.

Reporting group title	13vPnC + INFANRIX Hexa - After Infant Series

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series, assessed after the infant series blood draw up to toddler dose.

Reporting group title	13vPnC +INFANRIX Hexa + Paracetamol Twice Daily -Toddler Dose

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series and toddler dose (0.5 mL) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 366 to 425 days of age, along with paracetamol suspension 15 mg/kg orally at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of paracetamol, assessed from the toddler dose through the blood draw 28 to 42 days post toddler dose.

Reporting group title	13vPnC +INFANRIX Hexa + Ibuprofen Twice Daily -Toddler Dose

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series and toddler dose (0.5 mL) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 366 to 425 days of age, along with ibuprofen suspension 10 mg/kg orally at 6 to 8 hours after each vaccination and 6 to 8 hours after first dose of ibuprofen, assessed from the toddler dose through the blood draw 28 to 42 days post toddler dose.

Reporting group title	13vPnC +INFANRIX Hexa +Paracetamol Thrice Daily -Toddler Dose

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series and toddler dose (0.5 mL) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 366 to 425 days of age, along with paracetamol suspension 15 mg/kg orally immediately after each vaccination, 6 to 8 hours after each vaccination and 6 to 8 hours after last dose of paracetamol, assessed from the toddler dose through the blood draw 28 to 42 days post toddler dose.

Reporting group title	13vPnC +INFANRIX Hexa +Ibuprofen Thrice Daily -Toddler Dose

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series and toddler dose (0.5 mL) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 366 to 425 days of age, along with ibuprofen suspension 15 mg/kg orally immediately after each vaccination, 6 to 8 hours after each vaccination and 6 to 8 hours after last dose of ibuprofen,

assessed from the toddler dose through the blood draw 28 to 42 days post toddler dose.

Reporting group title	13vPnC + INFANRIX Hexa - Toddler Dose

Reporting group description:

Subjects who received 3 open-label doses (0.5 mL each) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions 28 to 42 days apart in infant series and toddler dose (0.5 mL) of 13vPnC intramuscularly and INFANRIX hexa intramuscularly as per manufacturer's instructions at 366 to 425 days of age, assessed from the toddler dose through the blood draw 28 to 42 days post toddler dose.

Serious adverse events	13vPnC+ INFANRIX Hexa +Paracetamol Twice Daily -Infant Series	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily -Infant Series	13vPnC+INFANRIX Hexa+Paracetamol Thrice Daily -Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 173 (4.05%)	3 / 176 (1.70%)	11 / 172 (6.40%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Thermal burn			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Exposure to toxic agent			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Congenital, familial and genetic disorders			
Ventricular septal defect			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Movement disorder			

subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	0 / 172 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (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 haemorrhagic			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Diarrhoea			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (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
Constipation			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal			

disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Pharyngitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Urinary tract infection			

subjects affected / exposed	1 / 173 (0.58%)	2 / 176 (1.14%)	1 / 172 (0.58%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 173 (1.16%)	0 / 176 (0.00%)	3 / 172 (1.74%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pertussis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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 acute			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Nasopharyngitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Laryngitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			

subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	2 / 173 (1.16%)	0 / 176 (0.00%)	0 / 172 (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
Bronchitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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 Escherichia coli			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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 rotavirus			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (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
Pyelonephritis			

subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC+ INFANRIX Hexa+ Ibuprofen Thrice Daily -Infant Series	13vPnC + INFANRIX Hexa - Infant Series	13vPnC +INFANRIX Hexa +Paracetamol Twice Daily -After Inf Ser
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 177 (4.52%)	10 / 210 (4.76%)	6 / 170 (3.53%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (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
Thermal burn			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Exposure to toxic agent			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Congenital, familial and genetic disorders			
Ventricular septal defect			

subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Movement disorder			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	1 / 170 (0.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (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 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (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
Constipation			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Hepatobiliary disorders			

Hyperbilirubinaemia			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	1 / 170 (0.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 177 (0.56%)	1 / 210 (0.48%)	2 / 170 (1.18%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Urinary tract infection			
subjects affected / exposed	2 / 177 (1.13%)	0 / 210 (0.00%)	0 / 170 (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			
subjects affected / exposed	2 / 177 (1.13%)	2 / 210 (0.95%)	1 / 170 (0.59%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pertussis			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (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
Otitis media acute			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (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 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (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
Lower respiratory tract infection			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (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
Laryngitis			

subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Exanthema subitum			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	1 / 170 (0.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (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
Bronchitis			
subjects affected / exposed	2 / 177 (1.13%)	0 / 210 (0.00%)	0 / 170 (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
Bronchiolitis			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (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
Bacterial infection			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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 Escherichia coli			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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 rotavirus			

subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (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
Pyelonephritis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	1 / 170 (0.59%)
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 tract infection viral			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily -After Inf Ser	13vPnC+INFANRIX Hexa +Paracetamol Thrice Daily -After Inf Ser	13vPnC +INFANRIX Hexa +Ibuprofen Thrice Daily -After Inf Ser
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 174 (8.05%)	10 / 172 (5.81%)	11 / 176 (6.25%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Thermal burn			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (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
Exposure to toxic agent			

subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Ventricular septal defect			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Movement disorder			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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	0 / 174 (0.00%)	1 / 172 (0.58%)	0 / 176 (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 haemorrhagic			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Diarrhoea			
subjects affected / exposed	1 / 174 (0.57%)	1 / 172 (0.58%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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

Rectal haemorrhage			
subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	0 / 176 (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
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	1 / 176 (0.57%)
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			
Dermatitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	4 / 174 (2.30%)	0 / 172 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Upper respiratory tract infection			

subjects affected / exposed	2 / 174 (1.15%)	0 / 172 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Urinary tract infection			
subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 174 (0.57%)	2 / 172 (1.16%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pertussis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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 acute			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Lower respiratory tract infection			

subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Laryngitis			
subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	0 / 176 (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
Exanthema subitum			
subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	0 / 176 (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
Bronchopneumonia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (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
Bronchitis			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	2 / 176 (1.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	1 / 176 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (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
Ear infection			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Escherichia coli			

subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	1 / 176 (0.57%)
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 rotavirus			
subjects affected / exposed	3 / 174 (1.72%)	1 / 172 (0.58%)	0 / 176 (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
Pyelonephritis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC + INFANRIX Hexa - After Infant Series	13vPnC +INFANRIX Hexa + Paracetamol Twice Daily -Toddler Dose	13vPnC +INFANRIX Hexa + Ibuprofen Twice Daily -Toddler Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 210 (4.29%)	3 / 169 (1.78%)	2 / 173 (1.16%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 210 (0.00%)	2 / 169 (1.18%)	0 / 173 (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
Thermal burn			

subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Exposure to toxic agent			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Congenital, familial and genetic disorders			
Ventricular septal defect			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Movement disorder			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Diarrhoea			
subjects affected / exposed	3 / 210 (1.43%)	0 / 169 (0.00%)	0 / 173 (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

Constipation			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (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 and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	1 / 173 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Pharyngitis			

subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	1 / 173 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (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
Urinary tract infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (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
Pertussis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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 acute			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Nasopharyngitis			

subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Laryngitis			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (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
Exanthema subitum			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Bronchopneumonia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Bronchitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (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
Bacterial infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			

subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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 Escherichia coli			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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 rotavirus			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (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
Pyelonephritis			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (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

Serious adverse events	13vPnC +INFANRIX Hexa +Paracetamol Thrice Daily -Toddler Dose	13vPnC +INFANRIX Hexa +Ibuprofen Thrice Daily -Toddler Dose	13vPnC + INFANRIX Hexa - Toddler Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 170 (0.59%)	1 / 175 (0.57%)	1 / 209 (0.48%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			

subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Thermal burn			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Exposure to toxic agent			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Congenital, familial and genetic disorders			
Ventricular septal defect			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Movement disorder			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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

Diarrhoea			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Constipation			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			

subjects affected / exposed	1 / 170 (0.59%)	0 / 175 (0.00%)	0 / 209 (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	0 / 170 (0.00%)	1 / 175 (0.57%)	0 / 209 (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			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Urinary tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Pertussis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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 acute			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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			

subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Nasopharyngitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Laryngitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Exanthema subitum			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Bronchopneumonia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Bronchitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Bacterial infection			

subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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 Escherichia coli			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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 rotavirus			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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
Pyelonephritis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (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

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	13vPnC+ INFANRIX Hexa +Paracetamol Twice Daily -Infant Series	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily -Infant Series	13vPnC+INFANRIX Hexa+Paracetamol Thrice Daily -Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	57 / 173 (32.95%)	71 / 176 (40.34%)	67 / 172 (38.95%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 173 (1.16%)	6 / 176 (3.41%)	5 / 172 (2.91%)
occurrences (all)	2	7	5
Vaccination site swelling			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Vaccination site nodule			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	1	0	0
Crying			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	1	0	0
Adverse drug reaction			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	49 / 149 (32.89%)	71 / 157 (45.22%)	27 / 147 (18.37%)
occurrences (all)	49	71	27
Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	2 / 138 (1.45%)	2 / 145 (1.38%)	1 / 137 (0.73%)
occurrences (all)	2	2	1
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence		

	from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[3]	37 / 141 (26.24%)	65 / 152 (42.76%)	30 / 140 (21.43%)
occurrences (all)	37	65	30
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[4]	2 / 133 (1.50%)	1 / 140 (0.71%)	2 / 134 (1.49%)
occurrences (all)	2	1	2
Fever ≥38°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[5]	30 / 136 (22.06%)	45 / 146 (30.82%)	23 / 135 (17.04%)
occurrences (all)	30	45	23
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[6]	2 / 129 (1.55%)	4 / 137 (2.92%)	1 / 125 (0.80%)
occurrences (all)	2	4	1
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[7]	0 / 128 (0.00%)	0 / 136 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Immune system disorders			
Food allergy subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Milk allergy subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0

Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	0	0	1
Psychiatric disorders			
Psychomotor retardation			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Apathy			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 173 (0.00%)	2 / 176 (1.14%)	3 / 172 (1.74%)
occurrences (all)	0	2	3
Weight increased			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Head injury			

subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Keratosis follicular			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Patent ductus arteriosus			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	0	0	1
Hydrocele			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Atrial septal defect			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	1	0	1
Nervous system disorders			
Hypertonia			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	1	0	1
Neuromyopathy			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	1 / 172 (0.58%)
occurrences (all)	0	1	1
Iron deficiency anaemia			

subjects affected / exposed	2 / 173 (1.16%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	2	0	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 173 (0.58%)	3 / 176 (1.70%)	7 / 172 (4.07%)
occurrences (all)	1	4	7
Dacryostenosis acquired			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 173 (0.58%)	2 / 176 (1.14%)	5 / 172 (2.91%)
occurrences (all)	1	2	5
Gingival pain			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Intestinal haemorrhage			

subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	1 / 172 (0.58%)
occurrences (all)	0	0	1
Aphthous stomatitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	3 / 172 (1.74%)
occurrences (all)	0	0	3
Abdominal pain			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	3 / 173 (1.73%)	1 / 176 (0.57%)	1 / 172 (0.58%)
occurrences (all)	3	1	1
Dermatitis atopic			
subjects affected / exposed	2 / 173 (1.16%)	2 / 176 (1.14%)	1 / 172 (0.58%)
occurrences (all)	2	2	1
Dermatitis diaper			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	1 / 172 (0.58%)
occurrences (all)	0	1	1

Rash			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Cafe au lait spots			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 173 (0.58%)	2 / 176 (1.14%)	1 / 172 (0.58%)
occurrences (all)	1	2	1
Skin depigmentation			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Hypercalciuria			

subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	1	0	0
Vesicoureteric reflux			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	9 / 173 (5.20%)	8 / 176 (4.55%)	11 / 172 (6.40%)
occurrences (all)	9	8	12
Coxsackie viral infection			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	1	0	0
Exanthema subitum			
subjects affected / exposed	0 / 173 (0.00%)	4 / 176 (2.27%)	1 / 172 (0.58%)
occurrences (all)	0	4	1
Gastroenteritis			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Laryngitis			

subjects affected / exposed	1 / 173 (0.58%)	2 / 176 (1.14%)	3 / 172 (1.74%)
occurrences (all)	1	2	3
Nasopharyngitis			
subjects affected / exposed	11 / 173 (6.36%)	6 / 176 (3.41%)	10 / 172 (5.81%)
occurrences (all)	14	7	11
Otitis media			
subjects affected / exposed	1 / 173 (0.58%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	1	1	0
Otitis media acute			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	4 / 173 (2.31%)	6 / 176 (3.41%)	5 / 172 (2.91%)
occurrences (all)	4	6	5
Respiratory tract infection			
subjects affected / exposed	4 / 173 (2.31%)	7 / 176 (3.98%)	4 / 172 (2.33%)
occurrences (all)	4	7	4
Rhinitis			
subjects affected / exposed	3 / 173 (1.73%)	7 / 176 (3.98%)	11 / 172 (6.40%)
occurrences (all)	3	7	11
Tonsillitis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	15 / 173 (8.67%)	12 / 176 (6.82%)	14 / 172 (8.14%)
occurrences (all)	16	12	15
Varicella			
subjects affected / exposed	1 / 173 (0.58%)	2 / 176 (1.14%)	0 / 172 (0.00%)
occurrences (all)	1	2	0
Viral infection			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 173 (1.16%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	3	1	0
Urinary tract infection			

subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	3 / 172 (1.74%)
occurrences (all)	0	1	3
Pneumonia			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis infective			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Bronchopneumonia			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Anal abscess			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	1 / 173 (0.58%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	2 / 172 (1.16%)
occurrences (all)	0	0	3
Lower respiratory tract infection			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Calcium metabolism disorder			
subjects affected / exposed	0 / 173 (0.00%)	0 / 176 (0.00%)	0 / 172 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	0 / 173 (0.00%)	1 / 176 (0.57%)	0 / 172 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	13vPnC+ INFANRIX Hexa+ Ibuprofen Thrice Daily -Infant Series	13vPnC + INFANRIX Hexa - Infant Series	13vPnC +INFANRIX Hexa +Paracetamol Twice Daily -After Inf Ser
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 177 (40.68%)	80 / 210 (38.10%)	3 / 170 (1.76%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 177 (1.13%)	2 / 210 (0.95%)	0 / 170 (0.00%)
occurrences (all)	2	2	0
Vaccination site swelling			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Vaccination site nodule			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Crying			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Adverse drug reaction			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Fever ≥38°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	53 / 155 (34.19%)	78 / 187 (41.71%)	0 / 170 (0.00%)
occurrences (all)	53	78	0
Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	1 / 146 (0.68%)	2 / 170 (1.18%)	0 / 170 (0.00%)
occurrences (all)	1	2	0

Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	70 / 159 (44.03%)	72 / 181 (39.78%)	0 / 170 (0.00%)
occurrences (all)	70	72	0
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	2 / 145 (1.38%)	6 / 164 (3.66%)	0 / 170 (0.00%)
occurrences (all)	2	6	0
Fever ≥38°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	47 / 141 (33.33%)	52 / 175 (29.71%)	0 / 170 (0.00%)
occurrences (all)	47	52	0
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	2 / 136 (1.47%)	3 / 167 (1.80%)	0 / 170 (0.00%)
occurrences (all)	2	3	0
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 135 (0.00%)	0 / 166 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Milk allergy			

subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Psychomotor retardation			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Apathy			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	1 / 177 (0.56%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	1	1	0
Weight increased			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Thermal burn			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Keratosis follicular			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Patent ductus arteriosus			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Atrial septal defect			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypertonia			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Hypotonia			
subjects affected / exposed	1 / 177 (0.56%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	1	1	0
Neuromyopathy			
subjects affected / exposed	1 / 177 (0.56%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	5 / 177 (2.82%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	5	0	0
Dacryostenosis acquired			
subjects affected / exposed	1 / 177 (0.56%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	2	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 177 (2.26%)	2 / 210 (0.95%)	0 / 170 (0.00%)
occurrences (all)	4	2	0
Gingival pain			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	2 / 177 (1.13%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	2	0	0
Toothache			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	1 / 170 (0.59%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Intestinal haemorrhage			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	2	0	0
Dyschezia			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	1 / 177 (0.56%)	2 / 210 (0.95%)	0 / 170 (0.00%)
occurrences (all)	1	2	0
Abdominal pain			
subjects affected / exposed	1 / 177 (0.56%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	1 / 177 (0.56%)	4 / 210 (1.90%)	1 / 170 (0.59%)
occurrences (all)	1	4	1

Dermatitis diaper			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Cafe au lait spots			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	1 / 170 (0.59%)
occurrences (all)	0	1	1
Dermatitis contact			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 177 (0.56%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	1	1	0
Skin depigmentation			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0

Renal and urinary disorders			
Hypercalciuria			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Vesicoureteric reflux			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	9 / 177 (5.08%)	5 / 210 (2.38%)	0 / 170 (0.00%)
occurrences (all)	9	5	0
Coxsackie viral infection			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	0 / 177 (0.00%)	2 / 210 (0.95%)	0 / 170 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			

subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	8 / 177 (4.52%)	18 / 210 (8.57%)	0 / 170 (0.00%)
occurrences (all)	9	21	0
Otitis media			
subjects affected / exposed	0 / 177 (0.00%)	2 / 210 (0.95%)	0 / 170 (0.00%)
occurrences (all)	0	2	0
Otitis media acute			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	4 / 177 (2.26%)	3 / 210 (1.43%)	0 / 170 (0.00%)
occurrences (all)	4	3	0
Respiratory tract infection			
subjects affected / exposed	5 / 177 (2.82%)	3 / 210 (1.43%)	0 / 170 (0.00%)
occurrences (all)	6	3	0
Rhinitis			
subjects affected / exposed	10 / 177 (5.65%)	9 / 210 (4.29%)	0 / 170 (0.00%)
occurrences (all)	11	10	0
Tonsillitis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	17 / 177 (9.60%)	12 / 210 (5.71%)	0 / 170 (0.00%)
occurrences (all)	19	15	0
Varicella			
subjects affected / exposed	3 / 177 (1.69%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	3	1	0
Viral infection			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 177 (0.56%)	2 / 210 (0.95%)	0 / 170 (0.00%)
occurrences (all)	1	2	0
Cystitis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Candidiasis			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Anal abscess			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	0 / 177 (0.00%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	1 / 177 (0.56%)	1 / 210 (0.48%)	0 / 170 (0.00%)
occurrences (all)	1	2	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Calcium metabolism disorder			
subjects affected / exposed	1 / 177 (0.56%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	1	0	0

Weight gain poor			
subjects affected / exposed	0 / 177 (0.00%)	0 / 210 (0.00%)	0 / 170 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC + INFANRIX Hexa + Ibuprofen Twice Daily -After Inf Ser	13vPnC+INFANRIX Hexa +Paracetamol Thrice Daily -After Inf Ser	13vPnC +INFANRIX Hexa +Ibuprofen Thrice Daily -After Inf Ser
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 174 (3.45%)	3 / 172 (1.74%)	4 / 176 (2.27%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	1	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Vaccination site nodule			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Crying			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Food allergy			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Milk allergy			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Genital labial adhesions			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Psychomotor retardation			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	1	0	0
Apathy			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Weight increased			

subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Keratosis follicular			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Patent ductus arteriosus			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Atrial septal defect			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypertonia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Neuromyopathy			

subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Intestinal haemorrhage			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	1	0	0

Dermatitis atopic			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Cafe au lait spots			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Skin depigmentation			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Hypercalciuria			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	1	0	0
Vesicoureteric reflux			
subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	1 / 174 (0.57%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	1	0	0
Muscle tightness			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			

subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	1 / 176 (0.57%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 174 (0.00%)	1 / 172 (0.58%)	0 / 176 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Viral infection			

subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Anal abscess			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Calcium metabolism disorder			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	0 / 176 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC + INFANRIX Hexa - After Infant Series	13vPnC +INFANRIX Hexa + Paracetamol Twice Daily -Toddler Dose	13vPnC +INFANRIX Hexa + Ibuprofen Twice Daily -Toddler Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 210 (3.81%)	47 / 169 (27.81%)	57 / 173 (32.95%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	3 / 173 (1.73%)
occurrences (all)	0	1	3
Vaccination site swelling			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Vaccination site nodule			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Crying			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 210 (0.00%)	42 / 133 (31.58%)	52 / 140 (37.14%)
occurrences (all)	0	42	52

Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[2]	0 / 210 (0.00%)	7 / 128 (5.47%)	9 / 127 (7.09%)
occurrences (all)	0	7	9
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[3]	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[4]	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[5]	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[6]	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[7]	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0

Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Psychomotor retardation			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Apathy			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	1 / 210 (0.48%)	1 / 169 (0.59%)	3 / 173 (1.73%)
occurrences (all)	1	1	3
Weight increased			

subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	1 / 173 (0.58%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	1 / 173 (0.58%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (0.00%)
occurrences (all)	0	1	0
Mouth injury			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Keratosis follicular			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	1	0	0
Patent ductus arteriosus			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Atrial septal defect			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypertonia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Neuromyopathy			

subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 210 (0.00%)	3 / 169 (1.78%)	1 / 173 (0.58%)
occurrences (all)	0	3	1
Gingival pain			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (0.00%)
occurrences (all)	0	1	0
Teething			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Intestinal haemorrhage			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	1	0	0

Dermatitis atopic			
subjects affected / exposed	0 / 210 (0.00%)	2 / 169 (1.18%)	0 / 173 (0.00%)
occurrences (all)	0	2	0
Dermatitis diaper			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	1 / 210 (0.48%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	1	0	0
Cafe au lait spots			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Skin depigmentation			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Hypercalciuria			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Vesicoureteric reflux			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 210 (0.48%)	2 / 169 (1.18%)	0 / 173 (0.00%)
occurrences (all)	1	2	0
Coxsackie viral infection			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (0.00%)
occurrences (all)	0	1	0
Exanthema subitum			
subjects affected / exposed	0 / 210 (0.00%)	2 / 169 (1.18%)	1 / 173 (0.58%)
occurrences (all)	0	2	1
Gastroenteritis			

subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 210 (0.48%)	1 / 169 (0.59%)	2 / 173 (1.16%)
occurrences (all)	1	1	2
Otitis media			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	1 / 173 (0.58%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	2 / 173 (1.16%)
occurrences (all)	0	1	2
Respiratory tract infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	1 / 173 (0.58%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 210 (0.00%)	2 / 169 (1.18%)	4 / 173 (2.31%)
occurrences (all)	0	2	4
Tonsillitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 210 (0.00%)	7 / 169 (4.14%)	7 / 173 (4.05%)
occurrences (all)	0	7	7
Varicella			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Viral infection			

subjects affected / exposed	0 / 210 (0.00%)	1 / 169 (0.59%)	0 / 173 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Anal abscess			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Calcium metabolism disorder			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	0 / 210 (0.00%)	0 / 169 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC +INFANRIX Hexa +Paracetamol Thrice Daily -Toddler Dose	13vPnC +INFANRIX Hexa +Ibuprofen Thrice Daily -Toddler Dose	13vPnC + INFANRIX Hexa - Toddler Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 170 (30.59%)	76 / 175 (43.43%)	50 / 209 (23.92%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 170 (0.59%)	3 / 175 (1.71%)	2 / 209 (0.96%)
occurrences (all)	1	3	2
Vaccination site swelling			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	2
Vaccination site nodule			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Crying			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	50 / 134 (37.31%)	72 / 144 (50.00%)	49 / 162 (30.25%)
occurrences (all)	50	72	49

Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[2]	5 / 118 (4.24%)	7 / 123 (5.69%)	3 / 150 (2.00%)
occurrences (all)	5	7	3
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[3]	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[4]	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[5]	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[6]	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systemic			
subjects affected / exposed[7]	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0

Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Psychomotor retardation			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Apathy			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Weight increased			

subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Head injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Mouth injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Keratosis follicular			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Patent ductus arteriosus			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Atrial septal defect			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypertonia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Neuromyopathy			

subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Dacryostenosis acquired			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 170 (0.59%)	5 / 175 (2.86%)	2 / 209 (0.96%)
occurrences (all)	1	5	2
Gingival pain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	3 / 170 (1.76%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	3	0	1
Teething			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	1 / 170 (0.59%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Intestinal haemorrhage			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 170 (0.00%)	1 / 175 (0.57%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	2 / 170 (1.18%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	2	0	0

Dermatitis atopic			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 170 (0.59%)	1 / 175 (0.57%)	0 / 209 (0.00%)
occurrences (all)	1	1	0
Rash papular			
subjects affected / exposed	0 / 170 (0.00%)	2 / 175 (1.14%)	0 / 209 (0.00%)
occurrences (all)	0	2	0
Rash pruritic			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Skin discolouration			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Cafe au lait spots			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Skin depigmentation			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Hypercalciuria			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Vesicoureteric reflux			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 170 (1.76%)	5 / 175 (2.86%)	2 / 209 (0.96%)
occurrences (all)	3	5	2
Coxsackie viral infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	4 / 170 (2.35%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	4	0	1
Gastroenteritis			

subjects affected / exposed	1 / 170 (0.59%)	1 / 175 (0.57%)	1 / 209 (0.48%)
occurrences (all)	1	1	1
Gastroenteritis viral			
subjects affected / exposed	1 / 170 (0.59%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	2 / 209 (0.96%)
occurrences (all)	0	0	2
Nasopharyngitis			
subjects affected / exposed	4 / 170 (2.35%)	2 / 175 (1.14%)	1 / 209 (0.48%)
occurrences (all)	4	2	1
Otitis media			
subjects affected / exposed	0 / 170 (0.00%)	1 / 175 (0.57%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	5 / 170 (2.94%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	5	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	6 / 175 (3.43%)	2 / 209 (0.96%)
occurrences (all)	0	6	2
Rhinitis			
subjects affected / exposed	5 / 170 (2.94%)	3 / 175 (1.71%)	5 / 209 (2.39%)
occurrences (all)	5	3	5
Tonsillitis			
subjects affected / exposed	1 / 170 (0.59%)	0 / 175 (0.00%)	1 / 209 (0.48%)
occurrences (all)	1	0	1
Upper respiratory tract infection			
subjects affected / exposed	3 / 170 (1.76%)	4 / 175 (2.29%)	7 / 209 (3.35%)
occurrences (all)	3	4	7
Varicella			
subjects affected / exposed	1 / 170 (0.59%)	1 / 175 (0.57%)	0 / 209 (0.00%)
occurrences (all)	1	1	0
Viral infection			

subjects affected / exposed	1 / 170 (0.59%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	1 / 175 (0.57%)	0 / 209 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Anal abscess			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Calcium metabolism disorder			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	0 / 170 (0.00%)	0 / 175 (0.00%)	0 / 209 (0.00%)
occurrences (all)	0	0	0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 June 2012	1-The Adverse Event Reporting section was updated in line with standards. 2-A section was added on medication errors.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported