Clinical trial results:
A Phase IIIB, Randomized, Open Label, Feasibility Study of a Single Priming Dose of Meningococcal Group C Conjugate Vaccine (NeisVac-C) in Infants

Summary

EudraCT number	2010-019383-36
Trial protocol	PL ES
Global end of trial date	31 January 2012

Results information

Result version number	v1
This version publication date	29 June 2016
First version publication date	05 August 2015

Trial information

Trial identification

Sponsor protocol code	670901

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01218451
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B9361011

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrails.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrails.gov_Inquiries@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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 July 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 January 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the feasibility of a single priming dose of NeisVac-C in infants (at either 4 or 6 months of age), as determined by immune response.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 September 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 835
Country: Number of subjects enrolled	Spain: 111
Worldwide total number of subjects	946
EEA total number of subjects	946

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)	946
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:

Study was conducted in Poland and Spain. Study was initiated on 28 Sep 2010 and completed on 31 Jan 2012.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	NeisVac-C: Group 1

Arm description:

Subjects recieved single dose of NeisVac-C at 4 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, and booster vaccination of all the vaccines between the age of 12 and 13 months.

Arm type	Experimental
Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A single 0.5 millilitre (mL) dose at 4 months of age, with booster vaccinations between 12 and 13 months 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:

0.5 mL Infanrix hexa at 2, 4 and 6 months of age, with booster vaccinations between 12 and 13 months of age.

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL Prevenar 13 at 2, 4 and 6 months of age, with booster vaccinations between 12 and 13 months of age.

Arm title	NeisVac-C: Group 2

Arm description:

Subjects recieved single dose of NeisVac-C at 6 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, and booster vaccination of all the vaccines between the age of 12 and 13 months.

Arm type	Experimental

Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A single 0.5mL dose at 6 months of age with booster vaccination between 12 and 13 months 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:

0.5 mL Infanrix hexa at 2, 4 and 6 months of age, with booster vaccinations between 12 and 13 months of age.

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL Prevenar 13 at 2, 4 and 6 months of age, with booster vaccinations between 12 and 13 months of age.

Arm title	NeisVac-C: Group 3

Arm description:

Subjects received two doses of NeisVac-C one each at 2 and 4 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, with booster vaccinations of all the vaccines between 12 and 13 months of age.

Arm type	Experimental
Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A single 0.5mL dose at either 2 or 4 month of age with booster vaccination between 12 and 13 months 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:

0.5 mL Infanrix hexa at 2, 4 and 6 months of age, with booster vaccinations between 12 and 13 months of age.

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL Prevenar 13 at 2, 4 and 6 months of age, with booster vaccinations between 12 and 13 months of age.

Number of subjects in period 1[1]	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3
Started	318	312	315
Completed	307	300	297
Not completed	11	12	18
Consent withdrawn by subject	1	4	9
Adverse event	3	1	2
Unspecified	7	2	3
Lost to follow-up	-	5	4

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: One subject was excluded from the safety analysis dataset because NeisVac-C vaccinations were administered at Months 2, 4 and 6.

Baseline characteristics

Reporting groups	
Reporting group title	NeisVac-C: Group 1
Reporting group description:	
Subjects recieved single dose of NeisVac-C at 4 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, and booster vaccination of all the vaccines between the age of 12 and 13 months.	
Reporting group title	NeisVac-C: Group 2
Reporting group description:	
Subjects recieved single dose of NeisVac-C at 6 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, and booster vaccination of all the vaccines between the age of 12 and 13 months.	
Reporting group title	NeisVac-C: Group 3
Reporting group description:	
Subjects received two doses of NeisVac-C one each at 2 and 4 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, with booster vaccinations of all the vaccines between 12 and 13 months of age.	

Reporting group values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3
Number of subjects	318	312	315
Age categorical Units: Subjects			
Age continuous Units: weeks arithmetic mean standard deviation	 7.7 ± 1.49	 7.6 ± 1.45	 7.7 ± 1.45
Gender categorical Units: Subjects			
Female	145	145	158
Male	173	167	157

Reporting group values	Total		
Number of subjects	945		
Age categorical Units: Subjects			
Age continuous Units: weeks arithmetic mean standard deviation	 -		
Gender categorical Units: Subjects			
Female	448		
Male	497		

End points

End points reporting groups

Reporting group title	NeisVac-C: Group 1
Reporting group description:	
Subjects recieved single dose of NeisVac-C at 4 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, and booster vaccination of all the vaccines between the age of 12 and 13 months.	
Reporting group title	NeisVac-C: Group 2
Reporting group description:	
Subjects recieved single dose of NeisVac-C at 6 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, and booster vaccination of all the vaccines between the age of 12 and 13 months.	
Reporting group title	NeisVac-C: Group 3
Reporting group description:	
Subjects received two doses of NeisVac-C one each at 2 and 4 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, with booster vaccinations of all the vaccines between 12 and 13 months of age.	

Primary: Proportion of Subjects With Seroprotective Antibody Titers 1 Month After Completion of the Primary Vaccination

End point title	Proportion of Subjects With Seroprotective Antibody Titers 1 Month After Completion of the Primary Vaccination
End point description:	
Number of subjects achieving seroprotective antibody titre (Serum bactericidal activity [rSBA] greater than or equal to [>=] 8), 1 month after the primary vaccination of NeisVac-C was reported. Per protocol analysis data set contained all randomized and vaccinated subjects who fulfilled the exclusion/inclusion criteria, had no major protocol deviation affecting the estimate of treatment effect and had immunogenicity measurements available for at least one of the three co-primary endpoints.	
End point type	Primary
End point timeframe:	
1 month after primary vaccination	

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	271	265	250	
Units: Proportion of subjects				
number (confidence interval 90%)	99.6 (98.3 to 100)	99.2 (97.6 to 99.9)	99.6 (98.1 to 100)	

Statistical analyses

Statistical analysis title	Response Rate (Group 2 vs Group 3)
Statistical analysis description:	
Non-inferiority margin was set to -10%. 90% Confidence Interval (CI) for the difference in the proportion of subjects with rSBA >= 8 was calculated between Group 2 and Group 3.	
Comparison groups	NeisVac-C: Group 3 v NeisVac-C: Group 2

Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in proportion
Point estimate	-0.4
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.9
upper limit	1.1

Statistical analysis title	Response Rate (Group 1 vs Group 3)

Statistical analysis description:

Non-inferiority margin was set to -10%. 90% CI for the difference in the proportion of subjects with rSBA >= 8 was calculated between Group 1 and Group 3.

Comparison groups	NeisVac-C: Group 1 v NeisVac-C: Group 3
Number of subjects included in analysis	521
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.3
upper limit	1.4

Primary: Proportion of Subjects With Seroprotective Antibody Titers Prior to the Administration of the Booster Dose

End point title	Proportion of Subjects With Seroprotective Antibody Titers Prior to the Administration of the Booster Dose

End point description:

Number of subjects achieving seroprotective antibody titre (rSBA >= 8) prior to the administration of the booster vaccination of NeisVac-C was reported. Per protocol analysis data set contained all randomized and vaccinated subjects who fulfilled the exclusion/inclusion criteria, had no major protocol deviation affecting the estimate of treatment effect and had immunogenicity measurements available for at least one of the three co-primary endpoints.

End point type	Primary

End point timeframe:

Before Booster Dose

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	264[1]	258[2]	245[3]	
Units: Proportion of subjects				
number (confidence interval 90%)	78 (73.4 to 82.2)	90.7 (87.2 to 93.5)	67.8 (62.5 to 72.7)	

Notes:

[1] - Number of subjects evaluable for this endpoint.

[2] - Number of subjects evaluable for this endpoint.

[3] - Number of subjects evaluable for this endpoint.

Statistical analyses

Statistical analysis title	Response Rate (Group 2 vs Group 3)
Statistical analysis description:	
Non-inferiority margin was set to -10%. 90% CI for the difference in the proportion of subjects with rSBA >= 8 was calculated between Group 2 and Group 3.	
Comparison groups	NeisVac-C: Group 2 v NeisVac-C: Group 3
Number of subjects included in analysis	503
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in proportion
Point estimate	22.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	17.2
upper limit	28.7

Statistical analysis title	Response Rate (Group 1 vs Group 3)
Statistical analysis description:	
Non-inferiority margin was set to -10%. 90% CI for the difference in the proportion of subjects with rSBA >= 8 was calculated between Group 1 and Group 3.	
Comparison groups	NeisVac-C: Group 1 v NeisVac-C: Group 3
Number of subjects included in analysis	509
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in proportion
Point estimate	10.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	3.8
upper limit	16.7

Primary: Proportion of Subjects With Seroprotective Antibody Titers 1 Month After the Administration of the Booster Dose.

End point title	Proportion of Subjects With Seroprotective Antibody Titers 1 Month After the Administration of the Booster Dose.

End point description:

Number of subjects achieving seroprotective antibody titre (rSBA >= 128), 1 month after the administration of booster vaccination of NeisVac-C was reported.The per protocol analysis data set contained all randomized and vaccinated subjects who fulfilled the exclusion/inclusion criteria, had no major protocol deviation affecting the estimate of treatment effect and had immunogenicity measurements available for at least one of the three co-primary endpoints.

End point type	Primary

End point timeframe:

1 month after booster dose

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	264[4]	258[5]	243[6]	
Units: Proportion of subjects				
number (confidence interval 90%)	98.9 (97.1 to 99.7)	99.6 (98.2 to 100)	99.6 (98.1 to 100)	

Notes:

[4] - Number of subjects evaluable for this endpoint.

[5] - Number of subjects evaluable for this endpoint.

[6] - Number of subjects evaluable for this endpoint.

Statistical analyses

Statistical analysis title	Response Rate (Group 2 vs Group 3)

Statistical analysis description:

Non-inferiority margin was set to -5%. 90% CI for the difference in the proportion of subjects with rSBA >= 128 was calculated between Group 2 and Group 3.

Comparison groups	NeisVac-C: Group 2 v NeisVac-C: Group 3
Number of subjects included in analysis	501
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.3
upper limit	1.5

Statistical analysis title	Response Rate (Group 1 vs Group 3)

Statistical analysis description:

Non-inferiority margin was set to -5%. 90% CI for the difference in the proportion of subjects with rSBA >= 128 was calculated between Group 1 and Group 3.

Comparison groups	NeisVac-C: Group 1 v NeisVac-C: Group 3

Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in proportion
Point estimate	-0.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.5
upper limit	0.8

Secondary: Geometric Mean Titer for Serum Bactericidal Activity (rSBA) 1 Month After Completion of the Primary Vaccination

End point title	Geometric Mean Titer for Serum Bactericidal Activity (rSBA) 1 Month After Completion of the Primary Vaccination

End point description:

rSBA titer 1 month after primary vaccination with NeisVac-C was reported. The immunogenicity analysis data set contained all randomized and vaccinated subjects (at least one vaccination with NeisVac-C) with available data for the immunogenicity analysis, i.e. with both baseline and at least one post-baseline immunogenicity measurement available.

End point type	Secondary

End point timeframe:

1 month after primary vaccination

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	315[7]	306[8]	301[9]	
Units: Titer				
geometric mean (confidence interval 95%)	372.1 (339.4 to 408.1)	401.8 (361.6 to 446.5)	624.1 (568.2 to 685.5)	

Notes:

[7] - Number of subjects evaluable for this endpoint.

[8] - Number of subjects evaluable for this endpoint.

[9] - Number of subjects evaluable for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean titer for Serum bactericidal Activity (rSBA) Prior to the Administration of the Booster Dose

End point title	Geometric Mean titer for Serum bactericidal Activity (rSBA) Prior to the Administration of the Booster Dose

End point description:

rSBA titers prior to the administration of booster dose of NeisVac-C was reported. The immunogenicity analysis data set contained all randomized and vaccinated subjects (at least one vaccination with NeisVac-C) with available data for the immunogenicity analysis, i.e. with both baseline and at least one post-baseline immunogenicity measurement available.

End point type	Secondary

End point timeframe:

Before Booster dose

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	297[10]	293[11]	285[12]	
Units: Titer				
geometric mean (confidence interval 95%)	38.5 (32.3 to 45.9)	84.8 (71.9 to 100.1)	29.5 (24.4 to 35.7)	

Notes:

[10] - Number of subjects evaluable for this endpoint.

[11] - Number of subjects evaluable for this endpoint.

[12] - Number of subjects evaluable for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer for Serum Bactericidal Activity (rSBA) 1 Month After the Administration of the Booster Dose.

End point title	Geometric Mean Titer for Serum Bactericidal Activity (rSBA) 1 Month After the Administration of the Booster Dose.

End point description:

rSBA titers after the administration of booster dose of NeisVac-C was reported. The immunogenicity analysis data set contained all randomized and vaccinated subjects (at least one vaccination with NeisVac-C) with available data for the immunogenicity analysis, i.e. with both baseline and at least one post-baseline immunogenicity measurement available.

End point type	Secondary

End point timeframe:

1 month after booster dose

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	302[13]	298[14]	288[15]	
Units: Titer				
geometric mean (confidence interval 95%)	2472.1 (2226.3 to 2745)	1874.8 (1684.4 to 2086.6)	1538 (1381.1 to 1712.6)	

Notes:

[13] - Number of subjects evaluable for this endpoint.

[14] - Number of subjects evaluable for this endpoint.

[15] - Number of subjects evaluable for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Prespecified Injection Site Reactions by Severity

End point title	Number of Subjects With Prespecified Injection Site Reactions by Severity

End point description:

Injection site reactions includes injection site pain, tenderness, redness, swelling, and induration. The severity of injection site reactions was rated for Redness, induration or swelling (diameter) as Mild (1.0–2.5 cm), Moderate (2.5.–5.0 cm) Severe (> 5.0 cm) and for Injection site pain or tenderness as Mild (No impairment of arm movement), Moderate (Impairment of arm movement) and Severe (Severe impairment, arm not moving). The safety analysis set contained all subjects vaccinated at least once with NeisVac-C.

End point type	Secondary

End point timeframe:

Within 3 days after primary, booster vaccination

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	312	315	
Units: Subjects				
number (not applicable)				
After primary vaccination (Mild)	97	92	128	
After primary vaccination (Moderate)	35	39	50	
After primary vaccination (Severe)	3	7	5	
After primary vaccination (Unknown)	25	20	24	
After booster vaccination (Mild)	92	74	81	
After booster vaccination (Moderate)	44	58	47	
After booster vaccination (Severe)	2	13	12	
After booster vaccination (Unknown)	14	14	20	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Prespecified Systemic Reactions by Severity

End point title	Number of Subjects With Prespecified Systemic Reactions by Severity

End point description:

Systemic reactions are treatment-related systemic adverse events. Systemic reactions were reported in subject diary and includes vomiting, sweating, inconsolable or persisting crying, irritability, sleepiness, and food rejection. The safety analysis set contained all subjects vaccinated at least once with NeisVac-C.

End point type	Secondary

End point timeframe:

Within 3 days after primary, booster vaccination

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	312	315	
Units: Subjects				
number (not applicable)				
After primary vaccination (Mild)	173	157	193	
After primary vaccination (Moderate)	28	16	52	
After primary vaccination (Severe)	0	0	2	
After primary vaccination (Unknown)	0	0	0	
After booster vaccination (Mild)	129	135	120	
After booster vaccination (Moderate)	23	30	25	
After booster vaccination (Severe)	1	0	0	
After booster vaccination (Unknown)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Adverse Events

End point title	Number of Subjects With Adverse Events

End point description:

An Adverse Event (AE) was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. A Serious AE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. All the adverse events excluding serious adverse events were also reported. The safety analysis set contained all subjects vaccinated at least once with NeisVac-C.

End point type	Secondary

End point timeframe:

Screening to 1 month after booster vaccination

End point values	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	312	315	
Units: Number of subjects				
number (not applicable)				
Serious AEs	50	38	34	
Any Non-Serious Systemic AEs	312	304	305	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Screening to 1 month after booster vaccination

Adverse event reporting additional description:

SAEs and AEs were grouped by system organ class and summarized. AEs included AEs collected in subject diary (local, systemic reactions) and AEs collected on case report form at each visit. MedDRA version was not captured, here 0.0 is included as dictionary version.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	NeisVac-C: Group 1

Reporting group description:

Subjects recieved single dose of NeisVac-C at 4 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, and booster vaccination of all the vaccines between the age of 12 and 13 months.

Reporting group title	NeisVac-C: Group 2

Reporting group description:

Subjects recieved single dose of NeisVac-C at 6 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, and booster vaccination of all the vaccines between the age of 12 and 13 months.

Reporting group title	NeisVac-C: Group 3

Reporting group description:

Subjects received two doses of NeisVac-C one each at 2 and 4 months of age along with Infanrix hexa and Prevenar 13 at 2, 4 and 6 months of age, with booster vaccinations of all the vaccines between 12 and 13 months of age.

Serious adverse events	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3
Total subjects affected by serious adverse events			
subjects affected / exposed	50 / 318 (15.72%)	38 / 312 (12.18%)	34 / 315 (10.79%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Nephroblastoma			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Phlebitis			

subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 318 (0.63%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Balanitis			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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			
Gene mutation			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Convulsion			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (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
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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
Enterocolitis			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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
Gastritis			

subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	0 / 315 (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
Gingivitis			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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
Intussusception			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (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
Stomatitis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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			
Hepatitis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (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 atopic			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (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
Erythema multiforme			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (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
Urticaria			

subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	4 / 318 (1.26%)	3 / 312 (0.96%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	8 / 318 (2.52%)	3 / 312 (0.96%)	3 / 315 (0.95%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	4 / 315 (1.27%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis infective			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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
Dermatitis infected			

subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (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	1 / 318 (0.31%)	0 / 312 (0.00%)	2 / 315 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	6 / 318 (1.89%)	8 / 312 (2.56%)	5 / 315 (1.59%)
occurrences causally related to treatment / all	0 / 6	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	5 / 318 (1.57%)	2 / 312 (0.64%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	1 / 318 (0.31%)	2 / 312 (0.64%)	0 / 315 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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
Laryngitis			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (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
Meningococcal sepsis			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			

subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	8 / 318 (2.52%)	8 / 312 (2.56%)	3 / 315 (0.95%)
occurrences causally related to treatment / all	0 / 8	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	0 / 315 (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
Pyelonephritis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	0 / 315 (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
Respiratory tract infection			
subjects affected / exposed	1 / 318 (0.31%)	3 / 312 (0.96%)	2 / 315 (0.63%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			

subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	0 / 315 (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
Urinary tract infection			
subjects affected / exposed	4 / 318 (1.26%)	4 / 312 (1.28%)	2 / 315 (0.63%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
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	NeisVac-C: Group 1	NeisVac-C: Group 2	NeisVac-C: Group 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	312 / 318 (98.11%)	304 / 312 (97.44%)	305 / 315 (96.83%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Haemangioma of skin			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Discomfort			

subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	2
Fatigue			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Injection site haematoma (Systemic)			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Injection site induration (Systemic)			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Injection site pain (Systemic)			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	2	0
Injection site swelling (Systemic)			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Irritability			
subjects affected / exposed	165 / 318 (51.89%)	187 / 312 (59.94%)	169 / 315 (53.65%)
occurrences (all)	320	373	328
Nodule			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	207 / 318 (65.09%)	206 / 312 (66.03%)	179 / 315 (56.83%)
occurrences (all)	385	413	350
Tenderness			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	2	0
Thirst			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Vaccination site reaction			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site haematoma			

subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Xerosis			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	179 / 318 (56.29%)	196 / 312 (62.82%)	195 / 315 (61.90%)
occurrences (all)	501	610	522
Injection site haematoma			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Injection site induration			
subjects affected / exposed	181 / 318 (56.92%)	204 / 312 (65.38%)	196 / 315 (62.22%)
occurrences (all)	567	692	522
Injection site inflammation			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Injection site oedema			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	2	0
Injection site pain			
subjects affected / exposed	144 / 318 (45.28%)	156 / 312 (50.00%)	153 / 315 (48.57%)
occurrences (all)	681	736	712
Injection site papule			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Injection site swelling			
subjects affected / exposed	130 / 318 (40.88%)	146 / 312 (46.79%)	136 / 315 (43.17%)
occurrences (all)	329	421	354
Injection site vesicles			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	2	0
Injection site warmth			

subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Puncture site reaction			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Injection site rash			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	3 / 315 (0.95%)
occurrences (all)	0	0	3
Food allergy			
subjects affected / exposed	0 / 318 (0.00%)	3 / 312 (0.96%)	2 / 315 (0.63%)
occurrences (all)	0	3	2
Milk allergy			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	1	0	1
Seasonal allergy			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Posthitis			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	0	1	2
Respiratory, thoracic and mediastinal disorders			
Allergic cough			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	1	0	1
Allergic respiratory symptom			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	2	0	0
Asthma			

subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Bronchial hyperreactivity			
subjects affected / exposed	0 / 318 (0.00%)	2 / 312 (0.64%)	1 / 315 (0.32%)
occurrences (all)	0	2	1
Bronchitis chronic			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	5
Cough			
subjects affected / exposed	5 / 318 (1.57%)	20 / 312 (6.41%)	14 / 315 (4.44%)
occurrences (all)	6	23	17
Dysphonia			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Interstitial lung disease			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 318 (0.00%)	2 / 312 (0.64%)	1 / 315 (0.32%)
occurrences (all)	0	2	1
Oropharyngeal pain			
subjects affected / exposed	0 / 318 (0.00%)	2 / 312 (0.64%)	1 / 315 (0.32%)
occurrences (all)	0	2	1
Pulmonary artery stenosis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	2	0	0
Rhinitis seasonal			

subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	2
Wheezing			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Apathy			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Decreased activity			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Food aversion			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Psychomotor retardation			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Restlessness			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	101 / 318 (31.76%)	119 / 312 (38.14%)	110 / 315 (34.92%)
occurrences (all)	152	180	171
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	0	1	1
Cardiac murmur			

subjects affected / exposed	3 / 318 (0.94%)	2 / 312 (0.64%)	2 / 315 (0.63%)
occurrences (all)	3	2	2
Cardiac murmur functional			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Animal scratch			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Burns second degree			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Clavicle fracture			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Eye injury			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Head injury			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Joint dislocation			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Limb injury			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	2 / 315 (0.63%)
occurrences (all)	0	0	2
Multiple injuries			

subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Nail injury			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Road traffic accident			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	1	0	1
Congenital, familial and genetic disorders			
Atrioventricular septal defect			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Craniotabes			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis congenital			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Hip dysplasia			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	0	1	1
Hydrocele			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	2 / 315 (0.63%)
occurrences (all)	0	0	2
Phimosis			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Plagiocephaly			

subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Coordination abnormal			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Crying			
subjects affected / exposed	139 / 318 (43.71%)	156 / 312 (50.00%)	139 / 315 (44.13%)
occurrences (all)	230	239	234
Hydrocephalus			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Hypertonia			
subjects affected / exposed	4 / 318 (1.26%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	4	1	0
Hypotonia			
subjects affected / exposed	2 / 318 (0.63%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	2	1	1
Somnolence			
subjects affected / exposed	116 / 318 (36.48%)	144 / 312 (46.15%)	124 / 315 (39.37%)
occurrences (all)	179	233	187
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 318 (1.26%)	9 / 312 (2.88%)	11 / 315 (3.49%)
occurrences (all)	4	9	15
Iron deficiency anaemia			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Lymphadenitis			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	2	0	1
Lymphadenopathy			
subjects affected / exposed	10 / 318 (3.14%)	4 / 312 (1.28%)	6 / 315 (1.90%)
occurrences (all)	10	4	6
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	2
Tympanic membrane hyperaemia			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctival irritation			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	28 / 318 (8.81%)	15 / 312 (4.81%)	16 / 315 (5.08%)
occurrences (all)	31	17	18
Dacryostenosis acquired			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Erythema of eyelid			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Eye discharge			
subjects affected / exposed	0 / 318 (0.00%)	3 / 312 (0.96%)	0 / 315 (0.00%)
occurrences (all)	0	4	0
Eye inflammation			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Strabismus			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	2 / 315 (0.63%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			

subjects affected / exposed	11 / 318 (3.46%)	12 / 312 (3.85%)	7 / 315 (2.22%)
occurrences (all)	13	13	8
Abdominal pain upper			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Abnormal faeces			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Aphthous stomatitis			
subjects affected / exposed	6 / 318 (1.89%)	3 / 312 (0.96%)	1 / 315 (0.32%)
occurrences (all)	6	3	1
Constipation			
subjects affected / exposed	6 / 318 (1.89%)	6 / 312 (1.92%)	7 / 315 (2.22%)
occurrences (all)	6	6	7
Diarrhoea			
subjects affected / exposed	27 / 318 (8.49%)	42 / 312 (13.46%)	29 / 315 (9.21%)
occurrences (all)	34	50	34
Dyspepsia			
subjects affected / exposed	0 / 318 (0.00%)	3 / 312 (0.96%)	2 / 315 (0.63%)
occurrences (all)	0	3	2
Enterocolitis			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Faeces discoloured			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	3 / 315 (0.95%)
occurrences (all)	1	1	4
Gastritis			
subjects affected / exposed	0 / 318 (0.00%)	2 / 312 (0.64%)	0 / 315 (0.00%)
occurrences (all)	0	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	2	0	1
Gingival pain			

subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	0	1	1
Gingivitis			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	1	1	1
Infantile colic			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	2 / 315 (0.63%)
occurrences (all)	1	1	2
Inguinal hernia			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	0	1	1
Mouth cyst			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Mucous stools			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Regurgitation			
subjects affected / exposed	3 / 318 (0.94%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	3	0	0
Stomatitis			
subjects affected / exposed	3 / 318 (0.94%)	2 / 312 (0.64%)	3 / 315 (0.95%)
occurrences (all)	4	2	4
Teething			
subjects affected / exposed	22 / 318 (6.92%)	25 / 312 (8.01%)	19 / 315 (6.03%)
occurrences (all)	35	47	31
Vomiting			
subjects affected / exposed	29 / 318 (9.12%)	25 / 312 (8.01%)	15 / 315 (4.76%)
occurrences (all)	34	31	15
Skin and subcutaneous tissue disorders			
Cafe au lait spots			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	1	1	1

Dermal cyst			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	3 / 318 (0.94%)	2 / 312 (0.64%)	6 / 315 (1.90%)
occurrences (all)	3	2	6
Dermatitis allergic			
subjects affected / exposed	15 / 318 (4.72%)	9 / 312 (2.88%)	13 / 315 (4.13%)
occurrences (all)	17	11	16
Dermatitis atopic			
subjects affected / exposed	31 / 318 (9.75%)	22 / 312 (7.05%)	21 / 315 (6.67%)
occurrences (all)	43	23	21
Dermatitis diaper			
subjects affected / exposed	6 / 318 (1.89%)	6 / 312 (1.92%)	5 / 315 (1.59%)
occurrences (all)	6	8	5
Dry skin			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	1	1	1
Eczema			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Heat rash			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	28 / 318 (8.81%)	41 / 312 (13.14%)	40 / 315 (12.70%)
occurrences (all)	36	52	58
Papule			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	8 / 318 (2.52%)	7 / 312 (2.24%)	9 / 315 (2.86%)
occurrences (all)	8	9	9

Rash macular			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Rash papular			
subjects affected / exposed	2 / 318 (0.63%)	2 / 312 (0.64%)	0 / 315 (0.00%)
occurrences (all)	2	2	0
Scab			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Scar			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	2	0	0
Seborrhoea			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	3 / 318 (0.94%)	2 / 312 (0.64%)	5 / 315 (1.59%)
occurrences (all)	3	2	5
Skin depigmentation			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	2 / 315 (0.63%)
occurrences (all)	1	4	2
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Urine odour abnormal			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Endocrine disorders			

Hypothyroidism			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Delayed fontanelle closure			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Facial asymmetry			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Rickets			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Torticollis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acute tonsillitis			
subjects affected / exposed	4 / 318 (1.26%)	1 / 312 (0.32%)	6 / 315 (1.90%)
occurrences (all)	5	2	7
Bacteriuria			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Bronchiolitis			
subjects affected / exposed	9 / 318 (2.83%)	8 / 312 (2.56%)	13 / 315 (4.13%)
occurrences (all)	12	12	16
Bronchitis			
subjects affected / exposed	69 / 318 (21.70%)	60 / 312 (19.23%)	48 / 315 (15.24%)
occurrences (all)	95	79	66
Candida nappy rash			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	3	1	0
Candidiasis			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	2	0	0
Conjunctivitis infective			

subjects affected / exposed	1 / 318 (0.31%)	4 / 312 (1.28%)	1 / 315 (0.32%)
occurrences (all)	1	5	1
Cystitis			
subjects affected / exposed	0 / 318 (0.00%)	2 / 312 (0.64%)	0 / 315 (0.00%)
occurrences (all)	0	2	0
Dacryocanaliculitis			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Dermatophytosis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	10 / 318 (3.14%)	4 / 312 (1.28%)	6 / 315 (1.90%)
occurrences (all)	14	4	8
Enterobiasis			
subjects affected / exposed	2 / 318 (0.63%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	2	1	0
Enterocolitis infectious			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	0	1	1
Erythema infectiosum			
subjects affected / exposed	0 / 318 (0.00%)	2 / 312 (0.64%)	0 / 315 (0.00%)
occurrences (all)	0	2	0
Escherichia infection			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Exanthema subitum			
subjects affected / exposed	23 / 318 (7.23%)	40 / 312 (12.82%)	29 / 315 (9.21%)
occurrences (all)	32	41	29
Fungal infection			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	1 / 318 (0.31%)	2 / 312 (0.64%)	1 / 315 (0.32%)
occurrences (all)	1	2	1
Gastroenteritis			

subjects affected / exposed	14 / 318 (4.40%)	18 / 312 (5.77%)	12 / 315 (3.81%)
occurrences (all)	15	19	14
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal infection			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Herpangina			
subjects affected / exposed	0 / 318 (0.00%)	2 / 312 (0.64%)	1 / 315 (0.32%)
occurrences (all)	0	2	1
Herpes dermatitis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	4 / 318 (1.26%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	4	0	1
Infection			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	6 / 318 (1.89%)	11 / 312 (3.53%)	6 / 315 (1.90%)
occurrences (all)	8	11	6
Lower respiratory tract infection			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Mononucleosis syndrome			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	70 / 318 (22.01%)	55 / 312 (17.63%)	62 / 315 (19.68%)
occurrences (all)	116	80	105
Oral candidiasis			

subjects affected / exposed	4 / 318 (1.26%)	6 / 312 (1.92%)	4 / 315 (1.27%)
occurrences (all)	6	6	5
Oral herpes			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	0	1	1
Otitis externa			
subjects affected / exposed	0 / 318 (0.00%)	3 / 312 (0.96%)	0 / 315 (0.00%)
occurrences (all)	0	3	0
Otitis media			
subjects affected / exposed	12 / 318 (3.77%)	13 / 312 (4.17%)	12 / 315 (3.81%)
occurrences (all)	15	15	16
Otitis media acute			
subjects affected / exposed	4 / 318 (1.26%)	1 / 312 (0.32%)	3 / 315 (0.95%)
occurrences (all)	4	1	3
Pertussis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	44 / 318 (13.84%)	48 / 312 (15.38%)	37 / 315 (11.75%)
occurrences (all)	49	67	46
Pharyngotonsillitis			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	7 / 318 (2.20%)	2 / 312 (0.64%)	3 / 315 (0.95%)
occurrences (all)	7	2	3
Pyelonephritis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Rash pustular			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	26 / 318 (8.18%)	21 / 312 (6.73%)	30 / 315 (9.52%)
occurrences (all)	33	26	32
Respiratory tract infection viral			

subjects affected / exposed	2 / 318 (0.63%)	5 / 312 (1.60%)	1 / 315 (0.32%)
occurrences (all)	2	6	2
Roseola			
subjects affected / exposed	5 / 318 (1.57%)	2 / 312 (0.64%)	1 / 315 (0.32%)
occurrences (all)	5	2	1
Scarlet fever			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Sialoadenitis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Skin bacterial infection			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Skin candida			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	0	1	1
Skin infection			
subjects affected / exposed	2 / 318 (0.63%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	3	0	1
Staphylococcal skin infection			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	6 / 318 (1.89%)	12 / 312 (3.85%)	6 / 315 (1.90%)
occurrences (all)	8	12	6
Tonsillitis streptococcal			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Tracheitis			
subjects affected / exposed	0 / 318 (0.00%)	4 / 312 (1.28%)	2 / 315 (0.63%)
occurrences (all)	0	4	2
Upper respiratory tract infection			
subjects affected / exposed	87 / 318 (27.36%)	78 / 312 (25.00%)	98 / 315 (31.11%)
occurrences (all)	145	126	159
Urinary tract infection			

subjects affected / exposed	11 / 318 (3.46%)	11 / 312 (3.53%)	8 / 315 (2.54%)
occurrences (all)	15	13	9
Varicella			
subjects affected / exposed	3 / 318 (0.94%)	6 / 312 (1.92%)	8 / 315 (2.54%)
occurrences (all)	3	6	8
Viral infection			
subjects affected / exposed	0 / 318 (0.00%)	6 / 312 (1.92%)	5 / 315 (1.59%)
occurrences (all)	0	6	5
Viral rash			
subjects affected / exposed	3 / 318 (0.94%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	3	0	0
Viral skin infection			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 318 (0.63%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	3	1	0
Vulvitis			
subjects affected / exposed	3 / 318 (0.94%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	4	1	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	1	0	3
Vulvovaginitis			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	1	1	0
Injection site pustule			
subjects affected / exposed	0 / 318 (0.00%)	1 / 312 (0.32%)	0 / 315 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Cow's milk intolerance			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	1	0	1
Decreased appetite			
subjects affected / exposed	107 / 318 (33.65%)	118 / 312 (37.82%)	113 / 315 (35.87%)
occurrences (all)	152	173	177

Dehydration			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Feeding disorder neonatal			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Increased appetite			
subjects affected / exposed	0 / 318 (0.00%)	2 / 312 (0.64%)	1 / 315 (0.32%)
occurrences (all)	0	2	1
Iron deficiency			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Lactose intolerance			
subjects affected / exposed	1 / 318 (0.31%)	0 / 312 (0.00%)	0 / 315 (0.00%)
occurrences (all)	1	0	0
Underweight			
subjects affected / exposed	0 / 318 (0.00%)	0 / 312 (0.00%)	1 / 315 (0.32%)
occurrences (all)	0	0	1
Weight gain poor			
subjects affected / exposed	1 / 318 (0.31%)	1 / 312 (0.32%)	1 / 315 (0.32%)
occurrences (all)	1	1	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported