



Clinical trial results:

A PHASE 3, RANDOMIZED, OPEN-LABEL TRIAL TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE FORMULATED IN MULTIDOSE VIALS GIVEN WITH ROUTINE PEDIATRIC VACCINATIONS IN HEALTHY INFANTS

Summary

EudraCT number	2012-000482-21
Trial protocol	Outside EU/EEA
Global end of trial date	01 September 2014

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	18 March 2015

Trial information

Trial identification

Sponsor protocol code	B4671001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01964716
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	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.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	13 February 2015
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the immune response induced by 13-valent pneumococcal conjugate vaccine (13vPnC) with 2-phenoxyethanol in multi-dose vials (MDVs) is noninferior to the immune response induced by 13vPnC without 2-phenoxyethanol in single-dose syringes (SDSs) as measured by serotype-specific immunoglobulin G (IgG) concentrations 1 month after 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	09 January 2014
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	Gambia: 500
Worldwide total number of subjects	500
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	500
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
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total number of subjects screened were 526, out of which 500 were enrolled in the study. The study was conducted in Gambia which started on 09 January 2014 and completed on 01 September 2014.

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	13vPnC Multi-dose Vial (MDV)

Arm description:

Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) with 2-phenoxyethanol (2-PE) in MDV intramuscularly at 8, 12 and 16 weeks of age.

Arm type	Experimental
Investigational medicinal product name	13-valent pneumococcal conjugate vaccine in a multidose vial
Investigational medicinal product code	PF-06414256
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received three doses of 0.5 mL of 13vPnC with 2-PE in MDV intramuscularly at 8, 12 and 16 weeks of age.

Arm title	13vPnC Single-Dose Syringe (SDS)
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Arm description:

Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) without 2-phenoxyethanol (2-PE) in single dose syringe (SDS) intramuscularly at 8, 12 and 16 weeks of age.

Arm type	Active comparator
Investigational medicinal product name	13-valent pneumococcal conjugate vaccine in Single-Dose Syringe
Investigational medicinal product code	PF-05208760
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received three doses of 0.5 mL of 13vPnC without 2-PE in single dose syringe (SDS) intramuscularly at 8, 12 and 16 weeks of age.

Number of subjects in period 1	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)
Started	250	250
Vaccinated Dose 1	250	250
Vaccinated Dose 2	249	248
Vaccinated Dose 3	247	244
Completed	245	244
Not completed	5	6
Consent withdrawn by subject	2	3
Death	1	-
No longer met eligibility criteria	1	1
Lost to follow-up	1	2

Baseline characteristics

Reporting groups

Reporting group title	13vPnC Multi-dose Vial (MDV)
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Reporting group description:

Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) with 2-phenoxyethanol (2-PE) in MDV intramuscularly at 8, 12 and 16 weeks of age.

Reporting group title	13vPnC Single-Dose Syringe (SDS)
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Reporting group description:

Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) without 2-phenoxyethanol (2-PE) in single dose syringe (SDS) intramuscularly at 8, 12 and 16 weeks of age.

Reporting group values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)	Total
Number of subjects	250	250	500
Age categorical Units: Subjects			

Age continuous Units: days arithmetic mean standard deviation	57.3 ± 8.6	56.9 ± 8.8	-
Gender categorical Units: Subjects			
Female	129	130	259
Male	121	120	241

End points

End points reporting groups

Reporting group title	13vPnC Multi-dose Vial (MDV)
Reporting group description: Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) with 2-phenoxyethanol (2-PE) in MDV intramuscularly at 8, 12 and 16 weeks of age.	
Reporting group title	13vPnC Single-Dose Syringe (SDS)
Reporting group description: Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) without 2-phenoxyethanol (2-PE) in single dose syringe (SDS) intramuscularly at 8, 12 and 16 weeks of age.	
Subject analysis set title	Screened Only
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects who were screened for this study but were not randomized, assessed between signing of informed consent form and before randomization.	

Primary: Percentage of Subjects Achieving a Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody concentration Greater Than or Equal To (\geq) 0.35 Microgram per Milliliter (mcg/mL) 1 Month After the Infant Series for Each Vaccine Group

End point title	Percentage of Subjects Achieving a Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody concentration Greater Than or Equal To (\geq) 0.35 Microgram per Milliliter (mcg/mL) 1 Month After the Infant Series for Each Vaccine Group
End point description: Percentage of subjects achieving predefined antibody threshold ≥ 0.35 mcg/mL along with the corresponding 95% confidence interval (CI) for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) are presented. Exact 2-sided confidence interval (Clopper and Pearson) based on the observed proportion of subjects. Evaluable immunogenicity population: eligible subjects who received vaccine (as randomized) at all 3 doses, had blood drawn within protocol-specified time frames, had at least 1 valid and determinate assay result for proposed analysis, had no major protocol violations. Here "n"= subjects with valid and determinate IgG concentration to the given serotype.	
End point type	Primary
End point timeframe: 1 month after the infant series	

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	245	244		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype 1 (n=245,244)	99.2 (97.1 to 99.9)	100 (98.5 to 100)		
Serotype 3 (n=245,243)	98.8 (96.5 to 99.7)	99.6 (97.7 to 100)		
Serotype 4 (n=245,244)	99.6 (97.7 to 100)	99.6 (97.7 to 100)		

Serotype 5 (n=245,244)	95.9 (92.6 to 98)	97.1 (94.2 to 98.8)		
Serotype 6A (n=243,244)	96.3 (93.1 to 98.3)	97.5 (94.7 to 99.1)		
Serotype 6B (n=245,244)	95.1 (91.6 to 97.4)	95.1 (91.6 to 97.4)		
Serotype 7F (n=245,244)	99.6 (97.7 to 100)	100 (98.5 to 100)		
Serotype 9V (n=245,244)	98 (95.3 to 99.3)	98.4 (95.9 to 99.6)		
Serotype 14 (n=245,244)	97.6 (94.7 to 99.1)	98.4 (95.9 to 99.6)		
Serotype 18C (n=245,244)	99.2 (97.1 to 99.9)	98 (95.3 to 99.3)		
Serotype 19A (n=245,244)	99.6 (97.7 to 100)	98.8 (96.4 to 99.7)		
Serotype 19F (n=245,244)	96.7 (93.7 to 98.6)	97.1 (94.2 to 98.8)		
Serotype 23F (n=245,244)	95.9 (92.6 to 98)	95.9 (92.6 to 98)		

Statistical analyses

Statistical analysis title	Serotype 1
Statistical analysis description:	
Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
Parameter estimate	percent difference
Point estimate	-0.8
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-3.4
upper limit	1.2

Notes:

[1] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 3
Statistical analysis description:	
Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)

Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[2]
Parameter estimate	percent difference
Point estimate	-0.8
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-3.7
upper limit	1.6

Notes:

[2] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 4
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Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

Comparison groups	13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[3]
Parameter estimate	percent difference
Point estimate	0
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-2.3
upper limit	2.4

Notes:

[3] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 5
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Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[4]
Parameter estimate	percent difference
Point estimate	-1.2
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-5.4
upper limit	2.8

Notes:

[4] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 6A
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
Parameter estimate	percent difference
Point estimate	-1.2
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-5.3
upper limit	2.6

Notes:

[5] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 6B
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[6]
Parameter estimate	percent difference
Point estimate	0
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-4.7
upper limit	4.7

Notes:

[6] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 7F
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)

Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[7]
Parameter estimate	percent difference
Point estimate	-0.4
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-2.7
upper limit	1.6

Notes:

[7] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 9V
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Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[8]
Parameter estimate	percent difference
Point estimate	-0.4
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-3.8
upper limit	2.8

Notes:

[8] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 14
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Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[9]
Parameter estimate	percent difference
Point estimate	-0.8
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-4.3
upper limit	2.5

Notes:

[9] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 18C
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[10]
Parameter estimate	percent difference
Point estimate	1.2
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-1.6
upper limit	4.5

Notes:

[10] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 19A
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[11]
Parameter estimate	percent difference
Point estimate	0.8
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-1.6
upper limit	3.6

Notes:

[11] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 19F
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)

Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[12]
Parameter estimate	percent difference
Point estimate	-0.4
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-4.4
upper limit	3.5

Notes:

[12] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

Statistical analysis title	Serotype 23F
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Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[13]
Parameter estimate	percent difference
Point estimate	0
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-4.3
upper limit	4.4

Notes:

[13] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

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

End point title	Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Infant Series for Each Vaccine Group
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End point description:

Antibody GMC for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) 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. CIs were back transformations of a confidence interval based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population: eligible subjects who received vaccine (as randomized) at all 3 doses, had blood drawn within protocol-specified time frames, had at least 1 valid and determinate assay result for proposed analysis, had no major protocol violations. Here "n"= subjects with valid and determinate IgG concentration to the given serotype.

End point type	Primary
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End point timeframe:

1 month after the infant series

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	245	244		
Units: microgram per milliliter (mcg/mL)				
geometric mean (confidence interval 95%)				
Serotype 1 (n=245,244)	4.59 (4.11 to 5.12)	4.45 (4.01 to 4.93)		
Serotype 3 (n=245,243)	1.38 (1.29 to 1.49)	1.74 (1.62 to 1.87)		
Serotype 4 (n=245,244)	5.3 (4.84 to 5.81)	5.28 (4.76 to 5.85)		
Serotype 5 (n=245,244)	2 (1.79 to 2.22)	1.98 (1.79 to 2.2)		
Serotype 6A (n=243,244)	2.25 (2.02 to 2.5)	2.19 (1.96 to 2.44)		
Serotype 6B (n=245,244)	3.42 (2.91 to 4.02)	3.24 (2.77 to 3.78)		
Serotype 7F (n=245,244)	3.92 (3.59 to 4.27)	4.18 (3.83 to 4.55)		
Serotype 9V (n=245,244)	2.83 (2.56 to 3.13)	2.75 (2.49 to 3.04)		
Serotype 14 (n=245,244)	4.78 (4.06 to 5.63)	4.96 (4.27 to 5.77)		
Serotype 18C (n=245,244)	3.47 (3.17 to 3.79)	2.72 (2.46 to 3)		
Serotype 19A (n=245,244)	6.49 (5.7 to 7.38)	6.44 (5.66 to 7.32)		
Serotype 19F (n=245,244)	5.19 (4.59 to 5.86)	5 (4.43 to 5.63)		
Serotype 23F (n=245,244)	2.61 (2.3 to 2.97)	2.17 (1.92 to 2.46)		

Statistical analyses

Statistical analysis title	Serotype 1
Statistical analysis description:	
Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[14]
Parameter estimate	GMC Ratio
Point estimate	1.03

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.87
upper limit	1.22

Notes:

[14] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 3
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Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[15]
Parameter estimate	GMC Ratio
Point estimate	0.79
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.71
upper limit	0.9

Notes:

[15] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 4
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Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[16]
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.86
upper limit	1.18

Notes:

[16] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[17]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.85
upper limit	1.19

Notes:

[17] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[18]
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.86
upper limit	1.22

Notes:

[18] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)

Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[19]
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.82
upper limit	1.36

Notes:

[19] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 7F
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Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[20]
Parameter estimate	GMC Ratio
Point estimate	0.94
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.82
upper limit	1.08

Notes:

[20] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 9V
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Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[21]
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.87
upper limit	1.21

Notes:

[21] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 14
Statistical analysis description:	
Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[22]
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.75
upper limit	1.24

Notes:

[22] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[23]
Parameter estimate	GMC Ratio
Point estimate	1.28
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	1.09
upper limit	1.49

Notes:

[23] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 19A
Statistical analysis description:	
Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[24]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.82
upper limit	1.24

Notes:

[24] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 19F
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Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[25]
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.85
upper limit	1.26

Notes:

[25] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Statistical analysis title	Serotype 23F
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Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	489
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[26]
Parameter estimate	GMC Ratio
Point estimate	1.2

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.98
upper limit	1.48

Notes:

[26] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

Primary: Number of Subjects Reporting Local Reaction Within 5 Days After Dose 1 in MDV and SDS Group

End point title	Number of Subjects Reporting Local Reaction Within 5 Days After Dose 1 in MDV and SDS Group ^[27]
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End point description:

Local reactions were reported within 5 days (Day 2 to Day 6) using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurt if gently touched; Moderate (hurt if gently touched with crying); Severe (caused limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.1 to 7.0 cm); Severe (greater than [$>$] 7.0 cm). Subject may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine.

End point type	Primary
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End point timeframe:

Within 5 days after Dose 1 (Day 2 to Day 6) of the infant series

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248 ^[28]	250		
Units: subjects				
Redness: Any	1	0		
Redness: Mild	1	0		
Redness: Moderate	0	0		
Redness: Severe	0	0		
Swelling: Any	1	0		
Swelling: Mild	1	0		
Swelling: Moderate	0	0		
Swelling: Severe	0	0		
Tenderness: Any	42	47		
Tenderness: Mild	32	37		
Tenderness: Moderate	13	14		
Tenderness: Severe	0	0		

Notes:

[28] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days.

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Local Reaction Within 5 Days After Dose 2 in MDV and SDS Group

End point title	Number of Subjects Reporting Local Reaction Within 5 Days After Dose 2 in MDV and SDS Group ^[29]
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End point description:

Local reactions were reported within 5 days (Day 2 to Day 6) using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurt if gently touched; Moderate (hurt if gently touched with crying); Severe (caused limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 cm to 2.0 cm); Moderate (2.1 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine. Here 'n' = subjects whose response was "Yes" for any day or "No" for all days for specified local reaction.

End point type	Primary
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End point timeframe:

Within 5 days after Dose 2 (Day 2 to Day 6) of the infant series

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248 ^[30]	247 ^[31]		
Units: subjects				
Redness: Any (n=247, 247)	2	0		
Redness: Mild (n=247, 247)	2	0		
Redness: Moderate (n=247, 247)	0	0		
Redness: Severe (n=247, 247)	0	0		
Swelling: Any (n=247, 247)	2	0		
Swelling: Mild (n=247, 247)	2	0		
Swelling: Moderate (n=247, 247)	1	0		
Swelling: Severe (n=247, 247)	0	0		
Tenderness: Any (n=248, 247)	34	32		
Tenderness: Mild (n=248, 247)	27	28		
Tenderness: Moderate (n=247, 247)	7	5		
Tenderness: Severe (n=247, 247)	0	0		

Notes:

[30] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

[31] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Local Reaction Within 5 Days After Dose 3 in MDV and SDS Group

End point title	Number of Subjects Reporting Local Reaction Within 5 Days After Dose 3 in MDV and SDS Group ^[32]
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End point description:

Local reactions were reported within 5 days (Day 2 to Day 6) using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurt if gently touched; Moderate (hurt if gently touched with crying); Severe (caused limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 cm to 2.0 cm); Moderate (2.1 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. Safety population included subjects who received

at least 1 dose of study vaccine.

End point type	Primary
End point timeframe:	
Within 5 days after Dose 3 (Day 2 to Day 6) of the infant series	

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	246 ^[33]	241 ^[34]		
Units: subjects				
Redness: Any	0	0		
Redness: Mild	0	0		
Redness: Moderate	0	0		
Redness: Severe	0	0		
Swelling: Any	0	0		
Swelling: Mild	0	0		
Swelling: Moderate	0	0		
Swelling: Severe	0	0		
Tenderness: Any	37	35		
Tenderness: Mild	30	32		
Tenderness: Moderate	9	4		
Tenderness: Severe	0	0		

Notes:

[33] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

[34] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Systemic Events Within 5 Days After Dose 1 in MDV and SDS Group

End point title	Number of Subjects Reporting Systemic Events Within 5 Days After Dose 1 in MDV and SDS Group ^[35]
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End point description:

Systemic events (any fever greater than or equal to [\geq] 38.0 degrees Celsius [C], decreased appetite was scaled as; Moderate (decreased oral intake); Severe (refusal to feed). Irritability scaled as; Mild (easily consolable); Moderate (requiring increased attention); Severe (Inconsolable, crying that cannot be comforted). Increased sleep was scale as; mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (Disabling not interested in usual daily activity) and use of antipyretic medication were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine. Here 'n' included subjects whose response was "Yes" for any day or "No" for all days for specified systemic event.

End point type	Primary
End point timeframe:	
Within 5 days after Dose 1 (Day 2 to Day 6) of infant series	

Notes:

[35] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	249 ^[36]	250		
Units: subjects				
Fever: ≥ 38.0 degrees C (n=248, 250)	9	7		
Fever: ≥ 38.0 but ≤ 39.0 degrees C (n=248, 250)	9	7		
Fever: > 39.0 but ≤ 40.0 degrees C (n=248, 250)	0	0		
Fever: > 40.0 degrees C (n=248, 250)	0	0		
Decreased appetite: Any (n=248, 250)	17	26		
Decreased appetite: Moderate (n=248, 250)	17	26		
Decreased appetite: Severe (n=248, 250)	0	0		
Irritability: Any (n=249, 250)	103	93		
Irritability: Mild (n=249, 250)	86	77		
Irritability: Moderate (n=248, 250)	19	17		
Irritability: Severe (n=248, 250)	0	0		
Increased sleep: Any (n=248, 250)	16	14		
Increased sleep: Mild (n=248, 250)	11	10		
Increased sleep: Moderate (n=248, 250)	6	4		
Increased sleep: Severe (n=248, 250)	0	0		
Use of antipyretic medication (n=248, 250)	55	58		

Notes:

[36] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Systemic Events Within 5 Days After Dose 2 in MDV and SDS Group

End point title	Number of Subjects Reporting Systemic Events Within 5 Days After Dose 2 in MDV and SDS Group ^[37]
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End point description:

Systemic events (≥ 38.0 degrees C, decreased appetite was scaled as; Moderate (decreased oral intake); Severe (refusal to feed). Irritability scaled as; Mild (easily consolable); Moderate (requiring increased attention); Severe (Inconsolable, crying that cannot be comforted). Increased sleep was scale as; mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (Disabling not interested in usual daily activity) and use of antipyretic medication were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine. Here 'n' included subjects whose response was "Yes" for any day or "No" for all days for specified systemic event.

End point type	Primary
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End point timeframe:

Within 5 days after Dose 2 (Day 2 to Day 6) of infant series

Notes:

[37] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248 ^[38]	247 ^[39]		
Units: subjects				
Fever: ≥ 38.0 degrees C (n=247, 247)	7	7		
Fever: ≥ 38.0 but ≤ 39.0 degrees C (n=247, 247)	7	7		
Fever: > 39.0 but ≤ 40.0 degrees C (n=247, 247)	1	0		
Fever: > 40.0 degrees C (n=247, 247)	0	0		
Decreased appetite: Any (n=247, 247)	28	18		
Decreased appetite: Moderate (n=247, 247)	28	18		
Decreased appetite: Severe (n=247, 247)	0	0		
Irritability: Any (n=248, 247)	93	83		
Irritability: Mild (n=248, 247)	75	67		
Irritability: Moderate (n=247, 247)	23	17		
Irritability: Severe (n=247, 247)	0	3		
Increased sleep: Any (n=247, 247)	24	14		
Increased sleep: Mild (n=247, 247)	20	12		
Increased sleep: Moderate (n=247, 247)	4	1		
Increased sleep: Severe (n=247, 247)	0	1		
Use of antipyretic medication (n=248, 247)	46	43		

Notes:

[38] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

[39] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Systemic Events Within 5 Days After Dose 3 in MDV and SDS Group

End point title	Number of Subjects Reporting Systemic Events Within 5 Days After Dose 3 in MDV and SDS Group ^[40]
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End point description:

Systemic events (any fever ≥ 38.0 degrees C, decreased appetite was scaled as; Moderate (decreased oral intake); Severe (refusal to feed). Irritability scaled as; Mild (easily consolable); Moderate (requiring increased attention); Severe (Inconsolable, crying that cannot be comforted). Increased sleep was scale as; mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (Disabling not interested in usual daily activity) and use of antipyretic medication were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine. Here 'n' included subjects whose response was "Yes" for any day or "No" for all days for specified systemic event.

End point type	Primary
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End point timeframe:

Within 5 days after Dose 3 (Day 2 to Day 6) of infant series

Notes:

[40] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	246 ^[41]	243 ^[42]		
Units: subjects				
Fever: >=38.0 degrees C (n=246, 241)	3	8		
Fever: >=38.0 but <=39.0 degrees C (n=246, 241)	3	7		
Fever: >39.0 but <=40.0 degrees C (n=246, 241)	0	1		
Fever: >40.0 degrees C (n=246, 241)	0	0		
Decreased appetite: Any (n=246, 242)	24	20		
Decreased appetite: Moderate (n=246, 242)	24	19		
Decreased appetite: Severe (n=246, 241)	0	1		
Irritability: Any (n=246, 243)	83	92		
Irritability: Mild (n=246, 242)	71	74		
Irritability: Moderate (n=246, 242)	15	18		
Irritability: Severe (n=246, 241)	1	5		
Increased sleep: Any (n=246, 241)	12	12		
Increased sleep: Mild (n=246, 241)	10	11		
Increased sleep: Moderate (n=246, 241)	2	1		
Increased sleep: Severe (n=246, 241)	1	0		
Use of antipyretic medication (n=246, 241)	34	36		

Notes:

[41] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

[42] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) in the Infant Series

End point title	Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) in the Infant Series ^[43]
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End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE 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. Treatment-emergent are events between first dose of study drug and up to 28 to 42 days after last dose that were absent before treatment or that worsened relative to pre-treatment state. Safety population included all subjects who received at least 1 dose of study vaccine.

End point type	Primary
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End point timeframe:

Dose 1 up to 28 to 42 Days after Dose 3

Notes:

[43] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	250	250		
Units: subjects				
AEs	123	127		
SAEs	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) Prior to Dose 1

End point title	Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) Prior to Dose 1 ^[44]
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End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE 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. Adverse events were also reported in subjects who provided consent but were not randomized in this study. The data of these subjects has been reported under 'Screened Only' arm. Safety population included subjects who received at least 1 dose of study vaccine.

End point type	Primary
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End point timeframe:

Informed consent up to Dose 1

Notes:

[44] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)	Screened Only	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	250	250	26	
Units: subjects				
AEs	2	0	9	
SAEs	0	0	0	

Statistical analyses

Secondary: Percentage of Subjects Achieving a Serotype-Specific Opsonophagocytic Activity (OPA) Titer \geq lower limit of quantitation (LLOQ) 1 Month After Infant Series

End point title	Percentage of Subjects Achieving a Serotype-Specific Opsonophagocytic Activity (OPA) Titer \geq lower limit of quantitation (LLOQ) 1 Month After Infant Series
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End point description:

Percentage of subjects achieving OPA Titer \geq lower limit of quantitation (LLOQ) along with 95% CI for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) are presented. The LLOQ in titers for each serotype was: Pn001, 18; Pn003, 12; Pn004, 21; Pn005, 29; Pn06A, 37; Pn06B, 43, Pn7F, 210; Pn09V, 345; Pn014, 35; Pn18C, 31; Pn19A, 18; Pn19F, 48; and Pn23F, 13. Exact 2-sided confidence interval (Clopper and Pearson) based on the observed proportion of subjects. Here "n"= Number of subjects with an antibody titer \geq LLOQ for the given serotype. Evaluable immunogenicity population: subjects who received vaccine (randomized) at all 3 doses, had blood drawn within protocol-specified time frames, had at least 1 valid and determinate assay result for proposed analysis, had no major protocol violations. OPA analysis was performed in a subset of randomly selected subjects from each group.

End point type	Secondary
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End point timeframe:

1 month after the infant series

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	160	160		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype 1 (n=159,160)	71.7 (64 to 78.5)	79.4 (72.3 to 85.4)		
Serotype 3 (n=160,160)	98.8 (95.6 to 99.8)	100 (97.7 to 100)		
Serotype 4 (n=159,159)	100 (97.7 to 100)	100 (97.7 to 100)		
Serotype 5 (n=160,159)	83.1 (76.4 to 88.6)	85.5 (79.1 to 90.6)		
Serotype 6A (n=160,160)	99.4 (96.6 to 100)	99.4 (96.6 to 100)		
Serotype 6B (n=156,155)	96.8 (92.7 to 99)	96.8 (92.6 to 98.9)		
Serotype 7F (n=159,160)	100 (97.7 to 100)	100 (97.7 to 100)		
Serotype 9V (n=158,160)	79.7 (72.6 to 85.7)	75 (67.6 to 81.5)		
Serotype 14 (n=157,160)	81.5 (74.6 to 87.3)	89.4 (83.5 to 93.7)		
Serotype 18C (n=159,160)	99.4 (96.5 to 100)	99.4 (96.6 to 100)		
Serotype 19A (n=160,160)	95.6 (91.2 to 98.2)	97.5 (93.7 to 99.3)		
Serotype 19F (n=158,159)	93.7 (88.7 to 96.9)	94.3 (89.5 to 97.4)		
Serotype 23F (n=159,160)	96.2 (92 to 98.6)	97.5 (93.7 to 99.3)		

Statistical analyses

Statistical analysis title	Serotype 1
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	-7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.2
upper limit	1.9

Statistical analysis title	Serotype 3
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	1.1

Statistical analysis title	Serotype 4
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)

Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	2.3

Statistical analysis title	Serotype 5
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.6
upper limit	5.7

Statistical analysis title	Serotype 6A
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	2.8

Statistical analysis title	Serotype 6B
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	4.6

Statistical analysis title	Serotype 7F
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	2.3

Statistical analysis title	Serotype 9V
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	4.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	14.1

Statistical analysis title	Serotype 14
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Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	-7.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.8
upper limit	0

Statistical analysis title	Serotype 18C
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Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	2.9

Statistical analysis title	Serotype 19A
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Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
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Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	-1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	2.4

Statistical analysis title	Serotype 19F
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	4.9

Statistical analysis title	Serotype 23F
Statistical analysis description: Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	percent difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.8
upper limit	3

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

End point title	Serotype-Specific Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After the Infant Series
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End point description:

Antibody geometric mean titers as measured by OPA assay for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) are presented. GMTs were calculated using all subjects with available data for the specified blood draw. CIs were back transformations of a confidence interval based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population: subjects who received vaccine (randomized) at all 3 doses, had blood drawn within protocol-specified time frames, had at least 1 valid and determinate assay result for proposed analysis, had no major protocol violations. OPA analysis was performed in a subset of randomly selected subjects from each group. Here "n"= subjects evaluable =specified category.

End point type	Secondary
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End point timeframe:

1 month after the infant series

End point values	13vPnC Multi-dose Vial (MDV)	13vPnC Single-Dose Syringe (SDS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	160	160		
Units: titer				
geometric mean (confidence interval 95%)				
Serotype 1 (n=159,160)	48 (39 to 58)	52 (43.2 to 62.6)		
Serotype 3 (n=160,160)	97 (87.3 to 108.8)	122 (110.1 to 135.7)		
Serotype 4 (n=159,159)	1666 (1412.3 to 1966.3)	1492 (1285.2 to 1732.3)		
Serotype 5 (n=160,159)	79 (67.7 to 92.4)	80 (69.1 to 92.6)		
Serotype 6A (n=160,160)	1690 (1460.5 to 1955.9)	1968 (1698.5 to 2279.3)		
Serotype 6B (n=156,155)	1990 (1611.7 to 2456.9)	2014 (1639.1 to 2475.4)		
Serotype 7F (n=159,160)	2891 (2565.4 to 3258.5)	3450 (3014.7 to 3947.9)		
Serotype 9V (n=158,160)	709 (600.5 to 836.2)	706 (597 to 835.3)		
Serotype 14 (n=157,160)	567 (415.4 to 773.5)	786 (607.8 to 1015.3)		
Serotype 18C (n=159,160)	2792 (2387.5 to 3264.8)	1605 (1352 to 1904.4)		
Serotype 19A (n=160,160)	305 (256.2 to 362.9)	329 (284.8 to 379.8)		
Serotype 19F (n=158,159)	430 (357.6 to 517.1)	470 (391.4 to 565.3)		
Serotype 23F (n=159,160)	918 (729 to 1156.4)	998 (810.6 to 1229.6)		

Statistical analyses

Statistical analysis title	Serotype 1
Statistical analysis description:	
Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.2

Statistical analysis title	Serotype 3
Statistical analysis description:	
Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.93

Statistical analysis title	Serotype 4
Statistical analysis description:	
Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)

Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.39

Statistical analysis title	Serotype 5
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Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.22

Statistical analysis title	Serotype 6A
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Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.06

Statistical analysis title	Serotype 6B
Statistical analysis description: Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.33

Statistical analysis title	Serotype 7F
Statistical analysis description: Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1

Statistical analysis title	Serotype 9V
Statistical analysis description: Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)

Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.27

Statistical analysis title	Serotype 14
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Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.08

Statistical analysis title	Serotype 18C
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Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.38
upper limit	2.19

Statistical analysis title	Serotype 19A
Statistical analysis description: Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.16

Statistical analysis title	Serotype 19F
Statistical analysis description: Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.18

Statistical analysis title	Serotype 23F
Statistical analysis description: Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).	
Comparison groups	13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV)

Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.25

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs)/serious AEs (SAEs): recorded from signing of informed consent form to 28 to 42 days after dose 3. Pre-specified AEs were recorded in an electronic diary: local reactions, systemic events (Day 2 to Day 6 after each vaccination).

Adverse event reporting additional description:

SAEs, AEs grouped by system organ class and summarized. AEs included AEs collected in electronic diary (local, systemic reactions; systematic assessment), events collected on case report form at each visit (non-systematic assessment). AEs also reported in subjects who provided consent but were not randomized (reported under 'Screened Only' arm).

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.1
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Reporting groups

Reporting group title	13vPnC MDV: Informed Consent to Dose 1
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Reporting group description:

Subjects who were randomized to receive 13vPnC (PF-06414256) MDV at 8, 12, and 16 weeks of age, assessed between signing of informed consent and before Dose 1.

Reporting group title	13vPnC SDS: Informed Consent to Dose 1
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Reporting group description:

Subjects who were randomized to receive 13vPnC (PF-05208760) SDS at 8, 12, and 16 weeks of age, assessed between signing of informed consent and before Dose 1.

Reporting group title	13vPnC MDV: After Dose 1
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Reporting group description:

Subjects who received single 0.5 mL dose of 13vPnC (PF-06414256) using MDV intramuscularly into the anterolateral thigh muscle of the left leg at 8 weeks of age, assessed after Dose 1 and before Dose 2.

Reporting group title	13vPnC SDS: After Dose 1
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Reporting group description:

Subjects who received single 0.5 mL dose of 13vPnC (PF-05208760) using SDS intramuscularly into the anterolateral thigh muscle of the left leg at 8 weeks of age, assessed after Dose 1 and before Dose 2.

Reporting group title	13vPnC MDV: After Dose 2
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Reporting group description:

Subjects who received two 0.5 mL doses of 13vPnC (PF-06414256) using MDV intramuscularly into the anterolateral thigh muscle of the left leg 8, 12 weeks of age, assessed after Dose 2 and before Dose 3.

Reporting group title	13vPnC SDS: After Dose 2
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Reporting group description:

Subjects who received two 0.5 mL doses of 13vPnC (PF-05208760) using SDS intramuscularly into the anterolateral thigh muscle of the left leg 8, 12 weeks of age, assessed after Dose 2 and before Dose 3.

Reporting group title	13vPnC MDV: After Dose 3
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Reporting group description:

Subjects who received all three 0.5mL doses of 13vPnC (PF-06414256) using MDV intramuscularly into the anterolateral thigh muscle of the left leg at 8 weeks of age, assessed after Dose 3 and up to blood draw at 4 weeks.

Reporting group title	13vPnC SDS: After Dose 3
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Reporting group description:

Subjects who received all three 0.5mL doses of 13vPnC (PF-05208760) using SDS intramuscularly into the anterolateral thigh muscle of the left leg at 8 weeks of age, assessed after Dose 3 and up to blood draw at 4 weeks.

Reporting group title	Screened Only
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Reporting group description:

Subjects who were screened for this study but were not randomized, assessed between signing of informed consent form and before randomization.

Serious adverse events	13vPnC MDV: Informed Consent to Dose 1	13vPnC SDS: Informed Consent to Dose 1	13vPnC MDV: After Dose 1
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Sudden infant death syndrome			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (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 SDS: After Dose 1	13vPnC MDV: After Dose 2	13vPnC SDS: After Dose 2
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Sudden infant death syndrome			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (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 MDV: After Dose 3	13vPnC SDS: After Dose 3	Screened Only
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 247 (0.40%)	0 / 244 (0.00%)	0 / 26 (0.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Sudden infant death syndrome			
subjects affected / exposed	1 / 247 (0.40%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	13vPnC MDV: Informed Consent to Dose 1	13vPnC SDS: Informed Consent to Dose 1	13vPnC MDV: After Dose 1
Total subjects affected by non-serious adverse events subjects affected / exposed	2 / 250 (0.80%)	0 / 250 (0.00%)	113 / 250 (45.20%)
Injury, poisoning and procedural complications			
Burns first degrees			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Heart disease congenital			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Umbilical granuloma			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	2 / 250 (0.80%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Decreased appetite: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed ^[1]	0 / 250 (0.00%)	0 / 250 (0.00%)	17 / 248 (6.85%)
occurrences (all)	0	0	17
Decreased appetite: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed ^[2] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	17 / 248 (6.85%) 17
Decreased appetite: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	0 / 248 (0.00%) 0
Fever: >=38.0 but <=39.0 degrees C	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	9 / 248 (3.63%) 9
Fever: >=38.0 degrees C	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	9 / 248 (3.63%) 9
Fever: >39.0 but <=40.0 degrees C	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[6] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	0 / 248 (0.00%) 0
Increased sleep: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	16 / 248 (6.45%) 16
Increased sleep: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	11 / 248 (4.44%) 11
Increased sleep: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	6 / 248 (2.42%) 6
Increased sleep: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[10] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	0 / 248 (0.00%) 0
Irritability: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	103 / 249 (41.37%) 103
Irritability: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[12] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	86 / 249 (34.54%) 86
Irritability: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[13] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	19 / 248 (7.66%) 19
Irritability: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is		

same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.

<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[14]</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 248 (0.00%)</p> <p>0</p>
<p>Pyrexia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>
<p>Ulcer</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>
<p>Vaccination site swelling</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>
<p>Gastrointestinal disorders</p> <p>Abdominal pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>1 / 250 (0.40%)</p> <p>1</p>
<p>Vomiting</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>3 / 250 (1.20%)</p> <p>3</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Bronchial hyperreactivity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>
<p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>2 / 250 (0.80%)</p> <p>2</p>
<p>Skin and subcutaneous tissue disorders</p> <p>Eczema</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>1 / 250 (0.40%)</p> <p>1</p>
<p>Dermatitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 250 (0.40%)</p> <p>1</p>	<p>0 / 250 (0.00%)</p> <p>0</p>	<p>8 / 250 (3.20%)</p> <p>8</p>

Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	1 / 250 (0.40%) 1
Rash papular subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0
Redness: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[15] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	1 / 248 (0.40%) 1
Redness: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[16] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	1 / 248 (0.40%) 1
Skin ulcer subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0
Swelling: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	1 / 248 (0.40%) 1
Swelling: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed ^[18]	0 / 250 (0.00%)	0 / 250 (0.00%)	1 / 248 (0.40%)
occurrences (all)	0	0	1
Swelling: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[19]	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Tenderness: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[20]	0 / 250 (0.00%)	0 / 250 (0.00%)	42 / 248 (16.94%)
occurrences (all)	0	0	42
Tenderness: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[21]	0 / 250 (0.00%)	0 / 250 (0.00%)	32 / 248 (12.90%)
occurrences (all)	0	0	32
Tenderness: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[22]	0 / 250 (0.00%)	0 / 250 (0.00%)	13 / 248 (5.24%)
occurrences (all)	0	0	13
Musculoskeletal and connective tissue disorders			
Growth retardation			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Atypical pneumonia			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	1 / 250 (0.40%)
occurrences (all)	0	0	1
Bronchopneumonia			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Chest wall abscess			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	3 / 250 (1.20%)
occurrences (all)	0	0	3
Dysentery			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Injection site abscess			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	1 / 250 (0.40%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	1 / 250 (0.40%)
occurrences (all)	0	0	1

Otitis media			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	1 / 250 (0.40%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	1 / 250 (0.40%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	1 / 250 (0.40%)
occurrences (all)	0	0	1
Tinea capitis			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	4 / 250 (1.60%)
occurrences (all)	0	0	4
Tinea faciei			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 250 (0.40%)	0 / 250 (0.00%)	27 / 250 (10.80%)
occurrences (all)	1	0	28
Urinary tract infection			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 250 (0.00%)	0 / 250 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0

Viral diarrhoea subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	6 / 250 (2.40%) 6
Viral infection subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	3 / 250 (1.20%) 3
Metabolism and nutrition disorders Failure to thrive subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0	0 / 250 (0.00%) 0

Non-serious adverse events	13vPnC SDS: After Dose 1	13vPnC MDV: After Dose 2	13vPnC SDS: After Dose 2
Total subjects affected by non-serious adverse events subjects affected / exposed	107 / 250 (42.80%)	114 / 249 (45.78%)	99 / 248 (39.92%)
Injury, poisoning and procedural complications Burns first degrees subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	1 / 250 (0.40%) 1	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	1 / 250 (0.40%) 1	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
Congenital, familial and genetic disorders Heart disease congenital subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
Pregnancy, puerperium and perinatal conditions Umbilical granuloma subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
General disorders and administration site conditions Decreased appetite: Any alternative dictionary used: Systemic Events 0.0	<div>Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.</div>		

alternative assessment type: Systematic			
subjects affected / exposed ^[1]	26 / 250 (10.40%)	28 / 247 (11.34%)	18 / 247 (7.29%)
occurrences (all)	26	28	18
Decreased appetite: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	26 / 250 (10.40%)	28 / 247 (11.34%)	18 / 247 (7.29%)
occurrences (all)	26	28	18
Decreased appetite: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	0 / 250 (0.00%)	0 / 247 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0	0
Fever: >=38.0 but <=39.0 degrees C	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	7 / 250 (2.80%)	7 / 247 (2.83%)	7 / 247 (2.83%)
occurrences (all)	7	7	7
Fever: >=38.0 degrees C	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[5]	7 / 250 (2.80%)	7 / 247 (2.83%)	7 / 247 (2.83%)
occurrences (all)	7	7	7
Fever: >39.0 but <=40.0 degrees C	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[6]	0 / 250 (0.00%)	1 / 247 (0.40%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Increased sleep: Any	Additional description: Subjects affected and occurrences for LRs and SEs is		

same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.			
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all)	14 / 250 (5.60%) 14	24 / 247 (9.72%) 24	14 / 247 (5.67%) 14
Increased sleep: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all)	10 / 250 (4.00%) 10	20 / 247 (8.10%) 20	12 / 247 (4.86%) 12
Increased sleep: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all)	4 / 250 (1.60%) 4	4 / 247 (1.62%) 4	1 / 247 (0.40%) 1
Increased sleep: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[10] occurrences (all)	0 / 250 (0.00%) 0	0 / 247 (0.00%) 0	1 / 247 (0.40%) 1
Irritability: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all)	93 / 250 (37.20%) 93	93 / 248 (37.50%) 93	83 / 247 (33.60%) 83
Irritability: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed ^[12]	77 / 250 (30.80%)	75 / 248 (30.24%)	67 / 247 (27.13%)
occurrences (all)	77	75	67
Irritability: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed ^[13]	17 / 250 (6.80%)	23 / 247 (9.31%)	17 / 247 (6.88%)
occurrences (all)	17	23	17
Irritability: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed ^[14]	0 / 250 (0.00%)	0 / 247 (0.00%)	3 / 247 (1.21%)
occurrences (all)	0	0	3
Pyrexia			
subjects affected / exposed	2 / 250 (0.80%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	2	0	0
Ulcer			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	1 / 248 (0.40%)
occurrences (all)	0	0	1
Vaccination site swelling			
subjects affected / exposed	1 / 250 (0.40%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	0 / 248 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	1 / 250 (0.40%)	0 / 249 (0.00%)	1 / 248 (0.40%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	0 / 248 (0.00%)
occurrences (all)	0	1	0
Cough			

subjects affected / exposed occurrences (all)	2 / 250 (0.80%) 2	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	1 / 248 (0.40%)
occurrences (all)	0	1	1
Dermatitis			
subjects affected / exposed	12 / 250 (4.80%)	5 / 249 (2.01%)	7 / 248 (2.82%)
occurrences (all)	12	5	7
Dermatitis atopic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	1 / 248 (0.40%)
occurrences (all)	0	0	1
Dermatitis diaper			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	1 / 248 (0.40%)
occurrences (all)	0	0	1
Redness: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[15] occurrences (all)	0 / 250 (0.00%) 0	2 / 247 (0.81%) 2	0 / 247 (0.00%) 0
Redness: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[16] occurrences (all)	0 / 250 (0.00%) 0	2 / 247 (0.81%) 2	0 / 247 (0.00%) 0
Skin ulcer			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Swelling: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all)	0 / 250 (0.00%) 0	2 / 247 (0.81%) 2	0 / 247 (0.00%) 0
Swelling: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all)	0 / 250 (0.00%) 0	2 / 247 (0.81%) 2	0 / 247 (0.00%) 0
Swelling: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[19] occurrences (all)	0 / 250 (0.00%) 0	0 / 247 (0.00%) 0	1 / 247 (0.40%) 1
Tenderness: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[20] occurrences (all)	47 / 250 (18.80%) 47	34 / 248 (13.71%) 34	32 / 247 (12.96%) 32
Tenderness: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[21] occurrences (all)	37 / 250 (14.80%) 37	27 / 248 (10.89%) 27	28 / 247 (11.34%) 28
Tenderness: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed ^[22] occurrences (all)	14 / 250 (5.60%) 14	7 / 247 (2.83%) 7	5 / 247 (2.02%) 5
Musculoskeletal and connective tissue disorders			
Growth retardation			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	0 / 248 (0.00%)
occurrences (all)	0	1	0
Bronchopneumonia			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	1 / 248 (0.40%)
occurrences (all)	0	0	1
Chest wall abscess			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	3 / 250 (1.20%)	3 / 249 (1.20%)	1 / 248 (0.40%)
occurrences (all)	3	3	1
Dysentery			
subjects affected / exposed	1 / 250 (0.40%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 250 (0.40%)	1 / 249 (0.40%)	0 / 248 (0.00%)
occurrences (all)	1	1	0
Gastroenteritis viral			

subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Injection site abscess			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	0 / 248 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	2 / 250 (0.80%)	2 / 249 (0.80%)	1 / 248 (0.40%)
occurrences (all)	2	2	1
Otitis media acute			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	0 / 248 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 250 (0.00%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	0 / 248 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	3 / 248 (1.21%)
occurrences (all)	0	1	3
Tinea capitis			
subjects affected / exposed	3 / 250 (1.20%)	3 / 249 (1.20%)	1 / 248 (0.40%)
occurrences (all)	3	3	1
Tinea faciei			
subjects affected / exposed	0 / 250 (0.00%)	1 / 249 (0.40%)	0 / 248 (0.00%)
occurrences (all)	0	1	0
Tinea infection			
subjects affected / exposed	1 / 250 (0.40%)	0 / 249 (0.00%)	0 / 248 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			

subjects affected / exposed occurrences (all)	1 / 250 (0.40%) 1	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	17 / 250 (6.80%) 17	17 / 249 (6.83%) 17	10 / 248 (4.03%) 10
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
Varicella subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0
Viral diarrhoea subjects affected / exposed occurrences (all)	10 / 250 (4.00%) 10	8 / 249 (3.21%) 8	10 / 248 (4.03%) 10
Viral infection subjects affected / exposed occurrences (all)	1 / 250 (0.40%) 1	1 / 249 (0.40%) 1	3 / 248 (1.21%) 3
Metabolism and nutrition disorders Failure to thrive subjects affected / exposed occurrences (all)	0 / 250 (0.00%) 0	0 / 249 (0.00%) 0	0 / 248 (0.00%) 0

Non-serious adverse events	13vPnC MDV: After Dose 3	13vPnC SDS: After Dose 3	Screened Only
Total subjects affected by non-serious adverse events subjects affected / exposed	97 / 247 (39.27%)	102 / 244 (41.80%)	9 / 26 (34.62%)
Injury, poisoning and procedural complications Burns first degrees subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	1 / 244 (0.41%) 1	0 / 26 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Congenital, familial and genetic disorders			

Heart disease congenital subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	1 / 26 (3.85%) 1
Pregnancy, puerperium and perinatal conditions Umbilical granuloma subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
General disorders and administration site conditions Decreased appetite: Any alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[1] occurrences (all)	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
Decreased appetite: Moderate alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all)	24 / 246 (9.76%) 24	20 / 242 (8.26%) 20	0 / 26 (0.00%) 0
Decreased appetite: Severe alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
Fever: >=38.0 but <=39.0 degrees C alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	24 / 246 (9.76%) 24	19 / 242 (7.85%) 19	0 / 26 (0.00%) 0
Fever: >=38.0 degrees C	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
	0 / 246 (0.00%) 0	1 / 241 (0.41%) 1	0 / 26 (0.00%) 0
	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
	3 / 246 (1.22%) 3	7 / 241 (2.90%) 7	0 / 26 (0.00%) 0
	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p>	3 / 246 (1.22%)	8 / 241 (3.32%)	0 / 26 (0.00%)
Fever: >39.0 but <=40.0 degrees C	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p>	0 / 246 (0.00%)	1 / 241 (0.41%)	0 / 26 (0.00%)
Increased sleep: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p>	12 / 246 (4.88%)	12 / 241 (4.98%)	0 / 26 (0.00%)
Increased sleep: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p>	10 / 246 (4.07%)	11 / 241 (4.56%)	0 / 26 (0.00%)
Increased sleep: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
<p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[9]</p> <p>occurrences (all)</p>	2 / 246 (0.81%)	1 / 241 (0.41%)	0 / 26 (0.00%)
Increased sleep: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[10]</p> <p>occurrences (all)</p>	1 / 246 (0.41%)	0 / 241 (0.00%)	0 / 26 (0.00%)
Irritability: Any	Additional description: Subjects affected and occurrences for LRs and SEs is		

same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.			
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all)	83 / 246 (33.74%) 83	92 / 243 (37.86%) 92	0 / 26 (0.00%) 0
Irritability: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[12] occurrences (all)	71 / 246 (28.86%) 71	74 / 242 (30.58%) 74	0 / 26 (0.00%) 0
Irritability: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[13] occurrences (all)	15 / 246 (6.10%) 15	18 / 242 (7.44%) 18	0 / 26 (0.00%) 0
Irritability: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[14] occurrences (all)	1 / 246 (0.41%) 1	5 / 241 (2.07%) 5	0 / 26 (0.00%) 0
Pyrexia			
subjects affected / exposed occurrences (all)	1 / 247 (0.40%) 1	1 / 244 (0.41%) 1	0 / 26 (0.00%) 0
Ulcer			
subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Vaccination site swelling			
subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Gastrointestinal disorders			

Abdominal pain subjects affected / exposed occurrences (all)	1 / 247 (0.40%) 1	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 247 (0.40%) 1	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Bronchial hyperreactivity subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Skin and subcutaneous tissue disorders Eczema subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Dermatitis subjects affected / exposed occurrences (all)	2 / 247 (0.81%) 2	6 / 244 (2.46%) 6	0 / 26 (0.00%) 0
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Dermatitis diaper subjects affected / exposed occurrences (all)	1 / 247 (0.40%) 1	2 / 244 (0.82%) 2	0 / 26 (0.00%) 0
Rash papular subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 244 (0.00%) 0	0 / 26 (0.00%) 0
Redness: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[15] occurrences (all)	0 / 246 (0.00%) 0	0 / 241 (0.00%) 0	0 / 26 (0.00%) 0
Redness: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is		

same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.			
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[16] occurrences (all)	0 / 246 (0.00%) 0	0 / 241 (0.00%) 0	0 / 26 (0.00%) 0
Skin ulcer subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	1 / 244 (0.41%) 1	0 / 26 (0.00%) 0
Swelling: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all)	0 / 246 (0.00%) 0	0 / 241 (0.00%) 0	0 / 26 (0.00%) 0
Swelling: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all)	0 / 246 (0.00%) 0	0 / 241 (0.00%) 0	0 / 26 (0.00%) 0
Swelling: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[19] occurrences (all)	0 / 246 (0.00%) 0	0 / 241 (0.00%) 0	0 / 26 (0.00%) 0
Tenderness: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[20] occurrences (all)	37 / 246 (15.04%) 37	35 / 241 (14.52%) 35	0 / 26 (0.00%) 0
Tenderness: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

0.0 is mentioned for dictionary version.			
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[21] occurrences (all)	30 / 246 (12.20%) 30	32 / 241 (13.28%) 32	0 / 26 (0.00%) 0
Tenderness: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[22] occurrences (all)	9 / 246 (3.66%) 9	4 / 241 (1.66%) 4	0 / 26 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Growth retardation			
subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	1 / 247 (0.40%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	1 / 247 (0.40%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	1 / 247 (0.40%)	4 / 244 (1.64%)	2 / 26 (7.69%)
occurrences (all)	1	5	2
Chest wall abscess			
subjects affected / exposed	1 / 247 (0.40%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	4 / 247 (1.62%)	3 / 244 (1.23%)	1 / 26 (3.85%)
occurrences (all)	4	3	1
Dysentery			

subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	3 / 247 (1.21%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	3	0	0
Gastroenteritis			
subjects affected / exposed	0 / 247 (0.00%)	1 / 244 (0.41%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	1 / 247 (0.40%)	1 / 244 (0.41%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Impetigo			
subjects affected / exposed	2 / 247 (0.81%)	1 / 244 (0.41%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
Injection site abscess			
subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 247 (0.40%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	3 / 247 (1.21%)	2 / 244 (0.82%)	0 / 26 (0.00%)
occurrences (all)	3	2	0
Otitis media acute			
subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 247 (0.00%)	2 / 244 (0.82%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Rash pustular			
subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	6 / 247 (2.43%)	3 / 244 (1.23%)	0 / 26 (0.00%)
occurrences (all)	6	3	0
Tinea capitis			

subjects affected / exposed	2 / 247 (0.81%)	1 / 244 (0.41%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
Tinea faciei			
subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	1 / 247 (0.40%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			
subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	19 / 247 (7.69%)	25 / 244 (10.25%)	0 / 26 (0.00%)
occurrences (all)	19	25	0
Urinary tract infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 244 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Varicella			
subjects affected / exposed	1 / 247 (0.40%)	0 / 244 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Viral diarrhoea			
subjects affected / exposed	5 / 247 (2.02%)	10 / 244 (4.10%)	0 / 26 (0.00%)
occurrences (all)	5	10	0
Viral infection			
subjects affected / exposed	0 / 247 (0.00%)	4 / 244 (1.64%)	0 / 26 (0.00%)
occurrences (all)	0	4	0
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 247 (0.00%)	1 / 244 (0.41%)	3 / 26 (11.54%)
occurrences (all)	0	1	3

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.

for all days.

[20] - 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.

[21] - 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.

[22] - 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? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported