Clinical trial results:
A Phase 4/3, Open-Label, Single-Arm, Multicenter Study to Describe the Safety and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine in Adults 50 to 65 Years of Age and in Children 6 to 17 Years of Age in India

Summary

EudraCT number	2014-001174-34
Trial protocol	Outside EU/EEA
Global end of trial date	31 July 2015

Results information

Result version number	v1 (current)
This version publication date	29 December 2016
First version publication date	29 December 2016

Trial information

Trial identification

Sponsor protocol code	B1851140

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02034877
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., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, 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	22 January 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 July 2015
Global end of trial reached?	Yes
Global end of trial date	31 July 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety profile of 13-valent Pneumococcal Conjugate vaccine (13vPnC) in adult subjects 50 to 65 years of age. To describe the safety profile of 13vPnC in pediatric subjects 6 to 17 years of age. To describe the immune responses to the 13 pneumococcal serotypes induced by13vPnC in a subset of approximately 400 adult subjects 50 to 65 years of age. To describe the immune responses to the 13 pneumococcal serotypes induced by 13vPnC in pediatric subjects 6 to 17 years of age.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 August 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	India: 1199
Worldwide total number of subjects	1199
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)	0
Children (2-11 years)	157
Adolescents (12-17 years)	43
Adults (18-64 years)	997
From 65 to 84 years	2

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1200 (200 pediatric and 1000 adult) subjects were randomized in the study. Out of the 1000 adult subjects, 999 subjects and all 200 pediatric subject received vaccination.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC (Pediatric Subjects)

Arm description:

Pediatric subjects aged 6 to 17 years received 1 single 0.5 milliliter (mL) dose of 13vPnC intramuscularly.

Arm type	Experimental
Investigational medicinal product name	13-valent pneumococcal conjugate vaccine (13vPnC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Pediatric subjects received 1 single 0.5 mL dose of 13vPnC intramuscularly.

Arm title	13vPnC (Adult Subjects)

Arm description:

Adult subjects aged 50 to 65 years received 1 single 0.5 mL dose of 13vPnC intramuscularly.

Arm type	Experimental
Investigational medicinal product name	13-valent pneumococcal conjugate vaccine (13vPnC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Adult subjects received 1 single 0.5 mL dose of 13vPnC intramuscularly.

Number of subjects in period 1	13vPnC (Pediatric Subjects)	13vPnC (Adult Subjects)
Started	200	999
Completed	200	993
Not completed	0	6
No Longer Willing to Participate	-	3
Lost to follow-up	-	3

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC (Pediatric Subjects)
Reporting group description:	
Pediatric subjects aged 6 to 17 years received 1 single 0.5 milliliter (mL) dose of 13vPnC intramuscularly.	
Reporting group title	13vPnC (Adult Subjects)
Reporting group description:	
Adult subjects aged 50 to 65 years received 1 single 0.5 mL dose of 13vPnC intramuscularly.	

Reporting group values	13vPnC (Pediatric Subjects)	13vPnC (Adult Subjects)	Total
Number of subjects	200	999	1199
Age categorical Units: Subjects			
Children (2-11 years)	157	0	157
Adolescents (12-17 years)	43	0	43
Adults (18-64 years)	0	997	997
From 65 to 84 years	0	2	2
Age continuous Units: years			
arithmetic mean	9.7	57.4	
standard deviation	± 2.62	± 4.29	-
Gender, Male/Female Units: Participants			
Female	107	414	521
Male	93	585	678

End points

End points reporting groups

Reporting group title	13vPnC (Pediatric Subjects)
Reporting group description:	
Pediatric subjects aged 6 to 17 years received 1 single 0.5 milliliter (mL) dose of 13vPnC intramuscularly.	
Reporting group title	13vPnC (Adult Subjects)
Reporting group description:	
Adult subjects aged 50 to 65 years received 1 single 0.5 mL dose of 13vPnC intramuscularly.	

Primary: Percentage of Subjects With Treatment-Emergent Adverse Events (AEs) or Serious Adverse Events (SAEs) Within 1 Month After 13vPnC Vaccination

End point title	Percentage of Subjects With Treatment-Emergent Adverse Events (AEs) or Serious Adverse Events (SAEs) Within 1 Month After 13vPnC Vaccination[1]
End point description:	
An AE was any untoward medical occurrence in a subjects 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 were events between first dose of study drug and up to 1 month after last dose that were absent before treatment or that worsened relative to pretreatment state. Safety population included all subjects who received 1 dose of 13vPnC vaccination.	
End point type	Primary
End point timeframe:	
Within 1 month after 13vPnC vaccination	
Notes:	
[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: No statistical analyses was planned for this primary endpoint	

End point values	13vPnC (Pediatric Subjects)	13vPnC (Adult Subjects)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	999		
Units: Percentage of subjects				
AEs	0	7		
SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) Before 13vPnC Vaccination

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) Before 13vPnC Vaccination[2]

End point description:

Antibody-mediated opsonophagocytic activity against each of 13 pneumococcal serotypes(1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F)were measured using a quantitative functional OPA assay. OPA titers were expressed as reciprocal of highest serum dilution that reduces survival of pneumococci by at least 50 percent (%).For each serotype, GMTs were calculated using logarithmically transformed assay results. Confidence intervals(CIs) for GMTs were back transformations of CI based on Student t distribution for mean of logarithmically transformed assay results.Evaluable immunogenicity population:eligible subjects received 13vPnC;had blood drawn within pre-specified time-frames with at least 1 valid,determinate assay result,no major protocol violation. Only 400 adults were selected for immunogenicity analysis.Here, 'n'=number of subjects with valid and determinate assay results for specified serotype. Number of subjects analyzed (N) signifies subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Before 13vPnC vaccination

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses was planned for this primary endpoint

End point values	13vPnC (Pediatric Subjects)	13vPnC (Adult Subjects)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	388		
Units: Titers				
geometric mean (confidence interval 95%)				
Serotype 1 (n=194, 385)	11 (9.6 to 11.8)	11 (10.4 to 11.7)		
Serotype 3 (n=197, 384)	18 (15.3 to 22.2)	10 (9.1 to 11.1)		
Serotype 4 (n=176, 358)	230 (155.8 to 339.2)	212 (165.7 to 271.3)		
Serotype 5 (n=199, 383)	19 (16.8 to 20.9)	17 (16.5 to 18.3)		
Serotype 6A (n=170, 347)	461 (339.6 to 626.8)	304 (255 to 363.5)		
Serotype 6B (n=163, 339)	263 (184.2 to 376.3)	331 (266.2 to 410.4)		
Serotype 7F (n=160, 363)	742 (585.8 to 940.5)	324 (289 to 363.9)		
Serotype 9V (n=183, 369)	2097 (1702.4 to 2582.9)	826 (730.8 to 933.4)		
Serotype 14 (n=182, 380)	1387 (1091 to 1763)	400 (335.9 to 476.3)		
Serotype 18C (n=154, 374)	216 (138.9 to 336.6)	213 (170.7 to 265.8)		
Serotype 19A (n=195, 383)	62 (47.2 to 80.1)	66 (56.4 to 76.2)		
Serotype 19F (n=194, 375)	265 (201.9 to 348.5)	115 (97.2 to 136.2)		
Serotype 23F (n=184, 379)	84 (58.3 to 121.4)	57 (45.5 to 71.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After 13vPnC Vaccination

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After 13vPnC Vaccination[3]

End point description:

Antibody-mediated opsonophagocytic activity against each of the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were measured using a quantitative functional OPA assay. OPA titers were expressed as the reciprocal of highest serum dilution that reduces survival of the pneumococci by at least 50%. For each serotype, GMTs were calculated using the logarithmically transformed assay results. CIs for GMTs were back transformations of a CI based on Student t distribution for the mean of the logarithmically transformed assay results. Evaluable immunogenicity population: eligible subjects received 13vPnC;had blood drawn within pre-specified time-frames with at least 1 valid,determinate assay result,no major protocol violation. Only 400 adults were selected for immunogenicity analysis. Here, 'n'=number of subjects with valid and determinate assay results for specified serotype. Number of subjects analyzed (N) signifies subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after 13vPnC vaccination

Notes:

[3] - 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: No statistical analyses was planned for this primary endpoint

End point values	13vPnC (Pediatric Subjects)	13vPnC (Adult Subjects)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	388		
Units: Titers				
geometric mean (confidence interval 95%)				
Serotype 1 (n=191, 376)	176 (146.1 to 212.7)	266 (231.4 to 304.6)		
Serotype 3 (n=200, 378)	118 (103.7 to 133.6)	143 (126.4 to 162.4)		
Serotype 4 (n=199, 371)	7860 (7074 to 8732.4)	6029 (5433 to 6691.4)		
Serotype 5 (n=200, 354)	286 (232.9 to 351.9)	639 (540.5 to 755.4)		
Serotype 6A (n=199, 376)	9247 (8197.4 to 10431.8)	6653 (5963.1 to 7423.8)		
Serotype 6B (n=195, 362)	6755 (6018.5 to 7581.7)	7690 (6844.8 to 8640.2)		
Serotype 7F (n=199, 378)	5251 (4787.9 to 5758.1)	3211 (2939.4 to 3507.2)		
Serotype 9V (n=197, 375)	7028 (6211.9 to 7951.1)	5441 (4954.6 to 5974.5)		
Serotype 14 (n=197, 379)	7484 (6586.1 to 8503.6)	3182 (2789.9 to 3628.6)		
Serotype 18C (n=198, 360)	8641 (7729 to 9661.2)	7670 (6818 to 8627.4)		
Serotype 19A (n=197, 380)	1928 (1660.6 to 2238.5)	2371 (2092.7 to 2686.6)		
Serotype 19F (n=200, 368)	3551 (3099.1 to 4069)	3340 (2937.7 to 3797.3)		
Serotype 23F (n=199, 378)	4419 (3945.7 to 4949.2)	5766 (5034.4 to 6604.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) From Before 13vPnC Vaccination to 1 Month After 13vPnC Vaccination

End point title	Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) From Before 13vPnC Vaccination to 1 Month After 13vPnC Vaccination[4]

End point description:

GMFRs for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from before 13vPnC vaccination to 1 month after 13vPnC vaccination were computed using the logarithmically transformed assay results. CIs for GMFRs were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both before and after vaccination blood draws. Evaluable immunogenicity population: eligible subjects received 13vPnC;had blood drawn within pre-specified time-frames with at least 1 valid,determinate assay result,no major protocol violation. Only 400 adults were selected for immunogenicity analysis. Here, 'n'=number of subjects with valid and determinate assay results for specified serotype. Number of subjects analyzed (N) signifies subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Before 13vPnC vaccination, 1 month after 13vPnC vaccination

Notes:

[4] - 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: No statistical analyses was planned for this primary endpoint

End point values	13vPnC (Pediatric Subjects)	13vPnC (Adult Subjects)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	388		
Units: Fold rise				
geometric mean (confidence interval 95%)				
Serotype 1 (n=185, 373)	16.3 (13.26 to 19.92)	24 (20.79 to 27.64)		
Serotype 3 (n=197, 374)	6.4 (5.23 to 7.8)	14.4 (12.49 to 16.63)		
Serotype 4 (n=175, 344)	32.6 (21.59 to 49.08)	27.6 (21.15 to 35.89)		
Serotype 5 (n=199, 351)	15.3 (12.15 to 19.26)	36.9 (31.18 to 43.6)		
Serotype 6A (n=169, 339)	19.1 (13.77 to 26.48)	23.1 (18.93 to 28.12)		
Serotype 6B (n=160, 316)	24.9 (17.19 to 35.94)	24.2 (19.35 to 30.27)		
Serotype 7F (n=160, 354)	7.1 (5.52 to 9.05)	9.5 (8.3 to 10.96)		
Serotype 9V (n=180, 358)	3.3 (2.65 to 4.1)	6.6 (5.75 to 7.48)		

Serotype 14 (n=179, 372)	5.5 (4.16 to 7.19)	7.8 (6.33 to 9.7)		
Serotype 18C (n=153, 350)	41.5 (26.82 to 64.25)	36.6 (28.69 to 46.68)		
Serotype 19A (n=192, 375)	31.2 (23.38 to 41.74)	36.3 (30.21 to 43.6)		
Serotype 19F (n=194, 358)	13.3 (9.87 to 17.99)	29.2 (23.64 to 35.98)		
Serotype 23F (n=183, 371)	53.3 (36.17 to 78.4)	102.7 (81.1 to 130.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With OPA Titer Greater Than or Equal to (>=) Lower Limit of Quantitation (LLOQ) Before 13vPnC Vaccination

End point title	Percentage of Subjects With OPA Titer Greater Than or Equal to (>=) Lower Limit of Quantitation (LLOQ) Before 13vPnC Vaccination[5]

End point description:

Percentage of subjects achieving serotype-specific pneumococcal OPA titer >=LLOQ, along with corresponding 95% CIs for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) are presented. Exact 2-sided CIs for were calculated using Clopper and Pearson method. LLOQ in titers for each serotype was: Pn001, 18; Pn003, 12; Pn004, 21; Pn005, 29; Pn06A, 37; Pn06B, 43; Pn7F, 210 (for adult subjects); Pn7F, 113 (for pediatric subjects) Pn09V, 345 (for adult subjects); Pn09V, 141 (for pediatric subjects); Pn014, 35; Pn18C, 31; Pn19A, 18; Pn19F, 48; Pn23F, 13. Evaluable immunogenicity population: eligible subjects received 13vPnC;had blood drawn within pre-specified time-frames with at least 1 valid,determinate assay result,no major protocol violation. Only 400 adults were selected for immunogenicity analysis. Here, 'n'=number of subjects with valid and determinate assay results for specified serotype and "N" signifies subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Before 13vPnC vaccination

Notes:

[5] - 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: No statistical analyses was planned for this primary endpoint

End point values	13vPnC (Pediatric Subjects)	13vPnC (Adult Subjects)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	388		
Units: Percentage of subjects				
number (confidence interval 95%)				
Serotype 1 (n=194, 385)	6.7 (3.6 to 11.2)	12.7 (9.6 to 16.5)		
Serotype 3 (n=197, 384)	50.8 (43.6 to 57.9)	25.8 (21.5 to 30.5)		
Serotype 4 (n=176, 358)	60.2 (52.6 to 67.5)	65.6 (60.5 to 70.6)		
Serotype 5 (n=199, 383)	12.1 (7.9 to 17.4)	13.1 (9.8 to 16.8)		
Serotype 6A (n=170, 347)	73.5 (66.2 to 80)	77.8 (73.1 to 82.1)		

Serotype 6B (n=163, 339)	55.8 (47.9 to 63.6)	68.7 (63.5 to 73.6)		
Serotype 7F (n=160, 363)	78.1 (70.9 to 84.3)	57.9 (52.6 to 63)		
Serotype 9V (n=183, 369)	90.2 (84.9 to 94.1)	74.5 (69.8 to 78.9)		
Serotype 14 (n=182, 380)	91.2 (86.1 to 94.9)	82.1 (77.9 to 85.8)		
Serotype 18C (n=154, 374)	50 (41.8 to 58.2)	67.6 (62.6 to 72.4)		
Serotype 19A (n=195, 383)	62.1 (54.8 to 68.9)	74.2 (69.5 to 78.5)		
Serotype 19F (n=194, 375)	66.5 (59.4 to 73.1)	54.4 (49.2 to 59.5)		
Serotype 23F (n=184, 379)	53.3 (45.8 to 60.6)	54.6 (49.5 to 59.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With OPA Titer Greater Than or Equal to (>=) Lower Limit of Quantitation (LLOQ) 1 Month After 13vPnC Vaccination

End point title	Percentage of Subjects With OPA Titer Greater Than or Equal to (>=) Lower Limit of Quantitation (LLOQ) 1 Month After 13vPnC Vaccination[6]

End point description:

Percentage of subjects achieving serotype-specific pneumococcal OPA titer >=LLOQ, along with corresponding 95% CIs for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) are presented. Exact 2-sided CIs were calculated using Clopper and Pearson method. LLOQ in titers for each serotype was: Pn001, 18; Pn003, 12; Pn004, 21; Pn005, 29; Pn06A, 37; Pn06B, 43; Pn7F, 210 (for adult subjects); Pn7F, 113 (for pediatric subjects) Pn09V, 345 (for adult subjects); Pn09V, 141 (for pediatric subjects); Pn014, 35; Pn18C, 31; Pn19A, 18; Pn19F, 48; Pn23F, 13. Evaluable immunogenicity population: eligible subjects received 13vPnC;had blood drawn within pre-specified time-frames with at least 1 valid,determinate assay result,no major protocol violation. Only 400 adults were selected for immunogenicity analysis. Here, 'n'=number of subjects with valid and determinate assay results for specified serotype and "N" signifies subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after 13vPnC vaccination

Notes:

[6] - 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: No statistical analyses was planned for this primary endpoint

End point values	13vPnC (Pediatric Subjects)	13vPnC (Adult Subjects)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	388		
Units: Percentage of subjects				
number (confidence interval 95%)				
Serotype 1 (n=191, 376)	92.7 (88 to 95.9)	94.9 (92.2 to 96.9)		
Serotype 3 (n=200, 378)	99.5 (97.2 to 100)	95.8 (93.2 to 97.6)		

Serotype 4 (n=199, 371)	100 (98.2 to 100)	100 (99 to 100)		
Serotype 5 (n=200, 354)	91 (86.1 to 94.6)	93.8 (90.7 to 96.1)		
Serotype 6A (n=199, 376)	100 (98.2 to 100)	100 (99 to 100)		
Serotype 6B (n=195, 362)	100 (98.1 to 100)	99.7 (98.5 to 100)		
Serotype 7F (n=199, 378)	100 (98.2 to 100)	99.2 (97.7 to 99.8)		
Serotype 9V (n=197, 375)	100 (98.1 to 100)	99.7 (98.5 to 100)		
Serotype 14 (n=197, 379)	100 (98.1 to 100)	98.7 (96.9 to 99.6)		
Serotype 18C (n=198, 360)	100 (98.2 to 100)	99.4 (98 to 99.9)		
Serotype 19A (n=197, 380)	99 (96.4 to 99.9)	99.5 (98.1 to 99.9)		
Serotype 19F (n=200, 368)	99 (96.4 to 99.9)	98.9 (97.2 to 99.7)		
Serotype 23F (n=199, 378)	100 (98.2 to 100)	98.9 (97.3 to 99.7)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Baseline to 1 month after 13vPnC vaccination (up to 42 days)	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1
Reporting groups	
Reporting group title	13vPnC (Adult Subjects)
Reporting group description: Adult subjects aged 50 to 65 years received 1 single 0.5 mL dose of 13vPnC intramuscularly.	
Reporting group title	13vPnC (Pediatric Subjects)
Reporting group description: Pediatric subjects aged 6 to 17 years received 1 single 0.5 mL dose of 13vPnC intramuscularly.	

Serious adverse events	13vPnC (Adult Subjects)	13vPnC (Pediatric Subjects)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 999 (0.00%)	0 / 200 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	13vPnC (Adult Subjects)	13vPnC (Pediatric Subjects)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	70 / 999 (7.01%)	0 / 200 (0.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Vaccination site pain			
subjects affected / exposed	46 / 999 (4.60%)	0 / 200 (0.00%)	
occurrences (all)	46	0	
Pyrexia			

subjects affected / exposed	22 / 999 (2.20%)	0 / 200 (0.00%)	
occurrences (all)	22	0	
Fatigue			
subjects affected / exposed	4 / 999 (0.40%)	0 / 200 (0.00%)	
occurrences (all)	4	0	
Chills			
subjects affected / exposed	2 / 999 (0.20%)	0 / 200 (0.00%)	
occurrences (all)	2	0	
Vaccination site erythema			
subjects affected / exposed	2 / 999 (0.20%)	0 / 200 (0.00%)	
occurrences (all)	2	0	
Vaccination site nodule			
subjects affected / exposed	2 / 999 (0.20%)	0 / 200 (0.00%)	
occurrences (all)	2	0	
Malaise			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
Vaccination site induration			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue			

disorders			
Joint range of motion decreased			
subjects affected / exposed	9 / 999 (0.90%)	0 / 200 (0.00%)	
occurrences (all)	9	0	
Myalgia			
subjects affected / exposed	4 / 999 (0.40%)	0 / 200 (0.00%)	
occurrences (all)	4	0	
Arthralgia			
subjects affected / exposed	4 / 999 (0.40%)	0 / 200 (0.00%)	
occurrences (all)	4	0	
Limb discomfort			
subjects affected / exposed	2 / 999 (0.20%)	0 / 200 (0.00%)	
occurrences (all)	2	0	
Pain in extremity			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Viral infection			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 999 (0.10%)	0 / 200 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 June 2013	To add immunogenicity objective for the adult group and to add a pediatric cohort.
15 September 2014	To change the study phase to 4/3 in the study title and throughout the protocol to reflect that the extension of the indication to children and adolescents aged 6 to 17 years is under review and not yet approved.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported