Clinical trial results:
A Phase 4, Open-label Study to Evaluate Persistence of the Antibody Response Elicited by Prevenar in Healthy Children in China Who Have Been Previously Immunized with a 4-dose Series of a Pneumococcal Conjugate Vaccine During Infancy in Study 0887x-101518

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

Summary

EudraCT number	2014-004179-22
Trial protocol	Outside EU/EEA
Global end of trial date	13 March 2011

Results information

Result version number	v2 (current)
This version publication date	28 July 2016
First version publication date	02 August 2015
Version creation reason	• Correction of full data set reporting periods and duplicate AEs in their data

Trial information

Trial identification

Sponsor protocol code	B1841009

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01298544
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: 6114A1-4001

Notes:

Sponsors

Sponsor organisation name	Pfizer
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	18 January 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 March 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to evaluate the antibody levels to the 7 pneumococcal vaccine serotypes at least 36 months after administration of the toddler vaccination in groups 1 and 2 in Wyeth study 0887X 101518, as measured by serotype specific immunoglobulin G (IgG) concentrations.

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	19 December 2010
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	China: 335
Worldwide total number of subjects	335
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)	335
Adolescents (12-17 years)	0
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All eligible subjects who completed a previous study, 0887X-101518 (NCT00488826), were invited to participate in this study, at a timepoint at least 3 years after their last vaccination in study 0887X-101518.

Pre-assignment

Screening details:

No vaccines administered during study. However, subjects assessed according to the vaccine group they were assigned to in study 0887X101518: 7-valent pneumococcal conjugate vaccine (7vPnC) alone (Group 1), 7vPnC given concomitantly with diphtheria, tetanus, and acellular pertussis vaccine (DTaP) (Group 2), or DTaP alone (Group 3).

Period 1

Period 1 title	Entire Study Population (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Entire Study Population

Arm description:

All randomized subjects.

Arm type	No intervention
Investigational medicinal product name	DTaP
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

No investigational product was administered during the Study. Subjects previously received DTaP in a preceding study, 0887X101518, at 3 months (vaccination 1), 4 months (vaccination 2), 5 months (vaccination 3) of age, with or without combination of 7vPnC at 3 months (vaccination 1), 4 months (vaccination 2), and 5 months (vaccination 3) and 12 to 15 months (vaccination 4) of age.

Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

No investigational product was administered during the Study. Subjects previously received 7vPnC in a preceding study, 0887X101518, at 3 months (vaccination 1), 4 months (vaccination 2), 5 months (vaccination 3), and 12 to 15 months (vaccination 4) of age, with or without combination of DTaP at 3 months (vaccination 1), 4 months (vaccination 2), and 5 months (vaccination 3) of age.

Number of subjects in period 1	Entire Study Population
Started	335
Completed	335

Baseline characteristics

Reporting groups	
Reporting group title	Entire Study Population

Reporting group description: -

Reporting group values	Entire Study Population	Total	
Number of subjects	335	335	
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	5.04		
standard deviation	± 0.15	-	
Gender, Male/Female Units: subjects			
Female	149	149	
Male	186	186	

End points

End points reporting groups

Reporting group title	Entire Study Population
Reporting group description:	
All randomized subjects.	
Subject analysis set title	DTaP Alone
Subject analysis set type	Per protocol
Subject analysis set description:	
No investigational product was administered during the study. Subjects previously received DTaP in a preceding study, 0887X101518, at 3 months (vaccination 1), 4 months (vaccination 2), and 5 months (vaccination 3).	
Subject analysis set title	7vPnC
Subject analysis set type	Per protocol
Subject analysis set description:	
No investigational product was administered during the study. Subjects previously received 7vPnC in a preceding study, 0887X101518, at 3 months (vaccination 1), 4 months (vaccination 2), 5 months (vaccination 3), and 12 to 15 months (vaccination 4) of age.	
Subject analysis set title	7vPnC and DTaP
Subject analysis set type	Per protocol
Subject analysis set description:	
No investigational product was administered during the study. Subjects previously received 7vPnC in a preceding study, 0887X101518, at 3 months (vaccination 1), 4 months (vaccination 2), 5 months (vaccination 3), and 12 to 15 months (vaccination 4) of age, with combination of DTaP at 3 months (vaccination 1), 4 months (vaccination 2), and 5 months (vaccination 3) of age.	

Primary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody, 36 Months After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody, 36 Months After the Toddler Dose
End point description:	
Antibody geometric mean concentration (GMC) as measured by mcg/mL for 7 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F). GMC (7vPnC, 7vPnC/DTaP, and DTap) and corresponding 2-sided 95% confidence intervals (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. Evaluable Immunogenicity population: eligible subjects who had blood drawn within required time frame, had at least 1 valid and determinate assay result for the proposed analysis, received no prohibited vaccines, and had no major protocol violations.	
End point type	Primary
End point timeframe:	
Day 1 (36 months after toddler dose)	

End point values	DTaP Alone	7vPnC	7vPnC and DTaP	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	91	123	121	
Units: microgram per milliliter (mcg/mL)				
geometric mean (confidence interval 95%)				
Serotype 4	0.41 (0.29 to 0.58)	0.98 (0.77 to 1.23)	0.66 (0.52 to 0.84)	

Serotype 6B	3.37 (2.76 to 4.13)	11.35 (9.71 to 13.27)	9.24 (7.66 to 11.16)	
Serotype 9V	1.05 (0.83 to 1.32)	1.35 (1.13 to 1.62)	1.29 (1.08 to 1.54)	
Serotype 14	0.55 (0.4 to 0.76)	4.5 (3.38 to 5.98)	3.02 (2.25 to 4.05)	
Serotype 18C	0.34 (0.24 to 0.47)	0.8 (0.66 to 0.97)	0.77 (0.6 to 0.98)	
Serotype 19F	1.7 (1.35 to 2.15)	10.14 (8.06 to 12.75)	5.67 (4.5 to 7.14)	
Serotype 23F	1.44 (1.17 to 1.76)	3.31 (2.8 to 3.91)	2.71 (2.26 to 3.25)	

Statistical analyses

Statistical analysis title	Serotype 4: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 2 - Group 1).

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	0.94

Statistical analysis title	Serotype 6B: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 2 - Group 1).

Comparison groups	7vPnC and DTaP v 7vPnC
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.04

Statistical analysis title	Serotype 9V: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 2 - Group 1).

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.23

Statistical analysis title	Serotype 14: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Ratio of GMC,s was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 2 - Group 1).

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.01

Statistical analysis title	Serotype 18C: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 2 - Group 1).

Comparison groups	7vPnC v 7vPnC and DTaP

Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.31

Statistical analysis title	Serotype 19F: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 2 - Group 1).

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.77

Statistical analysis title	Serotype 23F: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 2 - Group 1).

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.05

Statistical analysis title	Serotype 4: All groups
Statistical analysis description:	
Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 1 and 2 combined-Group 3).	
Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.39
upper limit	2.8

Statistical analysis title	Serotyope 6B: All groups
Statistical analysis description:	
Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 1 and 2 combined-Group 3).	
Comparison groups	7vPnC and DTaP v 7vPnC v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	3.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.41
upper limit	3.84

Statistical analysis title	Serotype 9V: All groups
Statistical analysis description:	
Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 1 and 2 combined-Group 3).	
Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	1.26

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.62

Statistical analysis title	Serotype 14: All groups

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 1 and 2 combined-Group 3).

Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	6.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.53
upper limit	9.79

Statistical analysis title	Serotype 18C: All groups

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 1 and 2 combined-Group 3).

Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	2.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.68
upper limit	3.24

Statistical analysis title	Serotype 19F: All groups

Statistical analysis description:

Ratio of GMC's was calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 1 and 2 combined-Group 3).

Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	4.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.29
upper limit	6.07

Statistical analysis title	Serotype 23F: All groups

Statistical analysis description:

Ratio of GMC's is calculated by back transforming the ratio difference between vaccine groups on logarithmic scale. Back transformations of CIs based on Student t distribution for ratio difference of the logarithms of the measures (Groups 1 and 2 combined-Group 3).

Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of GMC's
Point estimate	2.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.65
upper limit	2.63

Other pre-specified: Percentage of subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥0.35 mcg/mL, 36 Months After the Toddler Dose

End point title	Percentage of subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥0.35 mcg/mL, 36 Months After the Toddler Dose

End point description:

Percentage of subjects achieving predefined antibody threshold greater than or equal to (≥)0.35 mcg/mL along with the corresponding 95% CI for the 7 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F). Exact 2-sided CI based on the observed proportion of subjects. Evaluable Immunogenicity population.

End point type	Other pre-specified

End point timeframe:

Day 1 (36 months after toddler dose)

End point values	DTaP Alone	7vPnC	7vPnC and DTaP	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	91	123	121	
Units: Percentage of subjects				
number (confidence interval 95%)				
Serotype 4	48.8 (37.7 to 60)	82.9 (75.1 to 89.1)	64.5 (55.2 to 73)	
Serotype 6B	97.8 (92.3 to 99.7)	100 (97 to 100)	100 (97 to 100)	
Serotype 9V	83.5 (74.3 to 90.5)	93.5 (87.6 to 97.2)	94.2 (88.4 to 97.6)	
Serotype 14	63.7 (53 to 73.6)	95.1 (89.7 to 98.2)	91.7 (85.3 to 96)	
Serotype 18C	45.5 (34.8 to 56.4)	81.3 (73.3 to 87.8)	69.4 (60.4 to 77.5)	
Serotype 19F	92.2 (84.6 to 96.8)	100 (97 to 100)	97.5 (92.9 to 99.5)	
Serotype 23F	93.4 (86.2 to 97.5)	100 (97 to 100)	99.2 (95.5 to 100)	

Statistical analyses

Statistical analysis title	Serotype 4: 7vPnC vs 7vPnC and DTaP
Statistical analysis description:	
Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 2–Group 1), expressed as a percentage.	
Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-18.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.4
upper limit	-7.3

Statistical analysis title	Serotype 6B: 7vPnC vs 7vPnC and DTaP
Statistical analysis description:	
Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 2–Group 1), expressed as a percentage.	
Comparison groups	7vPnC v 7vPnC and DTaP

Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	3

Statistical analysis title	Serotype 9V: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 2–Group 1), expressed as a percentage.

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	7.3

Statistical analysis title	Serotype 14: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 2–Group 1), expressed as a percentage.

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	3.1

Statistical analysis title	Serotype 18C: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 2–Group 1), expressed as a percentage.

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-11.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.7
upper limit	-1

Statistical analysis title	Serotype 19F: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 2–Group 1), expressed as a percentage.

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	0.6

Statistical analysis title	Serotype 23F: 7vPnC vs 7vPnC and DTaP

Statistical analysis description:

Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 2–Group 1), expressed as a percentage.

Comparison groups	7vPnC v 7vPnC and DTaP
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	2.3

Statistical analysis title	Serotype 4: All groups
Statistical analysis description:	
Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 1 and 2 combined–Group 3), expressed as a percentage.	
Comparison groups	7vPnC v DTaP Alone v 7vPnC and DTaP
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	25
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.7
upper limit	37

Statistical analysis title	Serotype 6B: All groups
Statistical analysis description:	
Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 1 and 2 combined–Group 3), expressed as a percentage.	
Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	7.7

Statistical analysis title	Serotype 9V: All groups
Statistical analysis description:	
Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 1 and 2 combined–Group 3), expressed as a percentage.	
Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	10.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9
upper limit	19.6

Statistical analysis title	Serotype 14: All groups
Statistical analysis description:	
Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 1 and 2 combined–Group 3), expressed as a percentage.	
Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.4
upper limit	40.5

Statistical analysis title	Serotype 18C: All groups
Statistical analysis description:	
Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 1 and 2 combined–Group 3), expressed as a percentage.	
Comparison groups	7vPnC and DTaP v 7vPnC v DTaP Alone
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	30
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.9
upper limit	41.5

Statistical analysis title	Serotype 19F: All groups
Statistical analysis description:	
Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 1 and 2 combined–Group 3), expressed as a percentage.	
Comparison groups	7vPnC v 7vPnC and DTaP v DTaP Alone

Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	13.9

Statistical analysis title	Serotype 23F: All groups

Statistical analysis description:

Difference in proportions, expressed as a percentage. Exact 2 sided CI for the difference in proportions (Group 1 and 2 combined–Group 3), expressed as a percentage.

Comparison groups	7vPnC v DTaP Alone v 7vPnC and DTaP
Number of subjects included in analysis	335
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	6.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	13

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Time of informed consent to blood withdraw on day 1

Adverse event reporting additional description:

MedDRA dictionary version was not available, hence 0.0 is mentioned for dictionary version.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	Entire Study Population

Reporting group description:

All randomized subjects.

Serious adverse events	Entire Study Population		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 335 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Entire Study Population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 335 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No Serious Adverse Event or Non Serious Adverse Event had been reported during the study.

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