Clinical trial results:
A Phase III, Randomised, Open, Controlled, Multicentre, Primary Vaccination Study to Evaluate the Immunogenicity and Persistence of 1 and 2 Doses of Meningococcal Conjugate Vaccine MenACWY-TT in Toddlers (After 1 Month and up to 5 Years) and to Demonstrate Noninferiority of Co-Administration of MenACWY-TT and 13-Valent Pneumococcal Conjugate Vaccine Prevenar 13® Versus Separate Administration of the 2 Vaccines.

Summary

EudraCT number	2013-001083-28
Trial protocol	CZ
Global end of trial date	05 December 2019

Results information

Result version number	v1 (current)
This version publication date	25 September 2021
First version publication date	25 September 2021

Trial information

Trial identification

Sponsor protocol code	MENACWY-TT-104

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01939158
WHO universal trial number (UTN)	-
Other trial identifiers	C0921003: 116892

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	16 August 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the immunogenicity of MenACWY-TT after administration of 1 dose in vaccine groups ACWY1d and ACWY2d or 2 doses in vaccine group ACWY2d with respect to serum bactericidal assay using rabbit complement to measure activity against Neisseria meningitidis groups A, C, W-135, and Y (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, and rSBA-MenY) titers. To evaluate the long-term persistence of the immune response induced by 1 or 2 doses of MenACWY-TT with respect to rSBA-MenA, rSBA-MenC, rSBA-MenW-135, and rSBA-MenY titers.

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 Council for 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	02 October 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Safety
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Czechia: 206
Country: Number of subjects enrolled	Panama: 29
Country: Number of subjects enrolled	South Africa: 204
Country: Number of subjects enrolled	Turkey: 59
Country: Number of subjects enrolled	Australia: 167
Country: Number of subjects enrolled	Canada: 137
Worldwide total number of subjects	802
EEA total number of subjects	206

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)	802
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study was conducted from 2 October 2013 to 5 December 2019.

Pre-assignment

Screening details:

A total of 803 subjects were enrolled and were randomised in 1:1:1:1 ratio to either ACWY1d, ACWY2d, Co-ad and PCV13 groups. Of these, 1 subject was randomised but did not receive the study vaccine.

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	ACWY1d Group

Arm description:

Subjects received single dose of meningococcal polysaccharide groups A, C, W-135, and Y tetanus toxoid conjugate (MenACWY-TT) vaccine administered intramuscularly at Month 0.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received single dose of MenACWY-TT vaccine administered intramuscularly at Month 0.

Arm title	ACWY2d Group

Arm description:

Subjects received two doses of MenACWY-TT vaccine administered intramuscularly at Month 0 and Month 2.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received two doses of MenACWY-TT vaccine administered intramuscularly at Month 0 and Month 2.

Arm title	Co-ad Group

Arm description:

Subjects received single dose of MenACWY-TT vaccine and single dose of Prevnar 13 administered intramuscularly at Month 0.

Arm type	Experimental

Investigational medicinal product name	MenACWY-TT vaccine, Prevnar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received single dose of MenACWY-TT vaccine and single dose of Prevnar 13 administered intramuscularly at Month 0.

Arm title	PCV13 Group

Arm description:

Subjects received single dose of Prevnar 13 at Month 0 and single dose of MenACWY-TT administered intramuscularly at Month 2.

Arm type	Experimental
Investigational medicinal product name	Prevnar 13, MenACWY-TT vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received single dose of Prevnar 13 at Month 0 and single dose of MenACWY-TT administered intramuscularly at Month 2.

Number of subjects in period 1	ACWY1d Group	ACWY2d Group	Co-ad Group
Started	203	197	201
Completed	156	146	160
Not completed	47	51	41
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	22	24	15
Adverse event, non-fatal	1	-	-
No longer meets eligibility criteria	-	-	1
Migrated/moved from study area	5	7	3
Unspecified	1	3	4
Lost to follow-up	18	17	17

Number of subjects in period 1	PCV13 Group
Started	201
Completed	157
Not completed	44
Adverse event, serious fatal	1
Consent withdrawn by subject	17
Adverse event, non-fatal	-
No longer meets eligibility criteria	-
Migrated/moved from study area	6
Unspecified	3

Lost to follow-up	17

Baseline characteristics

Reporting groups	
Reporting group title	ACWY1d Group
Reporting group description:	
Subjects received single dose of meningococcal polysaccharide groups A, C, W-135, and Y tetanus toxoid conjugate (MenACWY-TT) vaccine administered intramuscularly at Month 0.	
Reporting group title	ACWY2d Group
Reporting group description:	
Subjects received two doses of MenACWY-TT vaccine administered intramuscularly at Month 0 and Month 2.	
Reporting group title	Co-ad Group
Reporting group description:	
Subjects received single dose of MenACWY-TT vaccine and single dose of Prevnar 13 administered intramuscularly at Month 0.	
Reporting group title	PCV13 Group
Reporting group description:	
Subjects received single dose of Prevnar 13 at Month 0 and single dose of MenACWY-TT administered intramuscularly at Month 2.	

Reporting group values	ACWY1d Group	ACWY2d Group	Co-ad Group
Number of subjects	203	197	201
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	203	197	201
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: months			
arithmetic mean	12.8	12.8	12.8
standard deviation	± 0.9	± 0.9	± 0.9
Sex: Female, Male Units: Subjects			
Female	94	85	98
Male	109	112	103
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	8	8	7
Not Hispanic or Latino	195	189	194
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	1

Asian	1	3	2
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	33	33	31
White	135	127	137
More than one race	34	34	29
Unknown or Not Reported	0	0	0

Reporting group values	PCV13 Group	Total	
Number of subjects	201	802	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	201	802	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous			
Units: months			
arithmetic mean	12.7		
standard deviation	± 0.9	-	
Sex: Female, Male			
Units: Subjects			
Female	98	375	
Male	103	427	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	8	31	
Not Hispanic or Latino	193	771	
Unknown or Not Reported	0	0	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	1	
Asian	3	9	
Native Hawaiian or Other Pacific Islander	1	2	
Black or African American	30	127	
White	134	533	
More than one race	33	130	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	ACWY1d Group
Reporting group description:	
Subjects received single dose of meningococcal polysaccharide groups A, C, W-135, and Y tetanus toxoid conjugate (MenACWY-TT) vaccine administered intramuscularly at Month 0.	
Reporting group title	ACWY2d Group
Reporting group description:	
Subjects received two doses of MenACWY-TT vaccine administered intramuscularly at Month 0 and Month 2.	
Reporting group title	Co-ad Group
Reporting group description:	
Subjects received single dose of MenACWY-TT vaccine and single dose of Prevnar 13 administered intramuscularly at Month 0.	
Reporting group title	PCV13 Group
Reporting group description:	
Subjects received single dose of Prevnar 13 at Month 0 and single dose of MenACWY-TT administered intramuscularly at Month 2.	

Primary: Percentage of Subjects With Serum Bactericidal Assay Using Rabbit Complement Antibody (rSBA) Titers >=1:8 at 1 Month After Administration of 1 Dose of MenACWY-TT in the ACWY1d, ACWY2d and Co-ad Groups

End point title	Percentage of Subjects With Serum Bactericidal Assay Using Rabbit Complement Antibody (rSBA) Titers >=1:8 at 1 Month After Administration of 1 Dose of MenACWY-TT in the ACWY1d, ACWY2d and Co-ad Groups[1][2]
End point description:	
Serogroups:Neisseria meningitidis serogroup A (MenA),Neisseria meningitidis serogroup C (MenC),Neisseria meningitidis serogroup W-135 (MenW-135),Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with rSBA titers >=1:8 against each serogroup at 1 month after administration of MenACWY-TT are reported. According-to-protocol (ATP) cohort for persistence Year 1:subjects who met all eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures, intervals in protocol, did not present with medical condition or received product leading to exclusion or non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at previous time point. "Number of Subjects Analysed"=subjects evaluable for this endpoint and ‘n’=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for PCV13 group.	
End point type	Primary
End point timeframe:	
1 month after administration of 1st dose of MenACWY-TT (i.e. at Month 1)	

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: Statistical analyses was not planned for this endpoint only descriptive data was planned.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	180	158	178	
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA (n=180, 158, 178)	97.8 (94.4 to 99.4)	96.8 (92.8 to 99.0)	94.9 (90.6 to 97.7)	
rSBA-MenC (n=179, 157, 176)	95.0 (90.7 to 97.7)	95.5 (91.0 to 98.2)	96.0 (92.0 to 98.4)	
rSBA-MenW-135 (n=180, 158, 177)	95.0 (90.7 to 97.7)	94.9 (90.3 to 97.8)	93.2 (88.5 to 96.4)	
rSBA-MenY (n=180, 157, 177)	92.8 (88.0 to 96.1)	93.6 (88.6 to 96.9)	89.8 (84.4 to 93.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With rSBA Titers >=1:8 at 1 Month After Administration of 2 Doses of MenACWY-TT in the ACWY2d Group

End point title	Percentage of Subjects With rSBA Titers >=1:8 at 1 Month After Administration of 2 Doses of MenACWY-TT in the ACWY2d Group[3][4]

End point description:

Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with rSBA titers >=1:8 against each serogroup at 1 month after administration of 2 doses of MenACWY-TT are reported. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. Here "number of subjects analysed" signifies subjects evaluable for this endpoint. Data for this endpoint was not planned to be collected and analysed for ACWY1d, Co-ad and PCV13 reporting groups.

End point type	Primary

End point timeframe:

1 month after administration of 2nd dose of MenACWY-TT (i.e. at Month 3)

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: Statistical analyses was not planned for this endpoint only descriptive data was planned.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY2d Group			
Subject group type	Reporting group			
Number of subjects analysed	150			
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA	98.0 (94.3 to 99.6)			
rSBA-MenC	98.7 (95.3 to 99.8)			

rSBA-MenW-135	100.0 (97.6 to 100.0)			
rSBA-MenY	99.3 (96.3 to 100.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at Year 1 in the ACWY1d and ACWY2d Groups

End point title	Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at Year 1 in the ACWY1d and ACWY2d Groups[5][6]

End point description:

Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with rSBA titers >=1:8 and >=1:128 against each serogroup at Year 1 after administration of MenACWY-TT are reported. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. Here "number of subjects analysed" signifies subjects evaluable for this endpoint. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 reporting groups.

End point type	Primary

End point timeframe:

At Year 1

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: Statistical analyses was not planned for this endpoint only descriptive data was planned.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	167	143		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8	63.5 (55.7 to 70.8)	70.6 (62.4 to 77.9)		
rSBA-MenC: >=1:8	49.1 (41.3 to 56.9)	55.2 (46.7 to 63.6)		
rSBA-MenW-135: >=1:8	65.3 (57.5 to 72.5)	77.6 (69.9 to 84.2)		
rSBA-MenY: >=1:8	73.1 (65.7 to 79.6)	79.7 (72.2 to 86.0)		
rSBA-MenA: >=1:128	44.9 (37.2 to 52.8)	50.3 (41.9 to 58.8)		
rSBA-MenC: >=1:128	21.0 (15.1 to 27.9)	27.3 (20.2 to 35.3)		
rSBA-MenW-135: >=1:128	46.7 (39.0 to 54.6)	60.1 (51.6 to 68.2)		
rSBA-MenY: >=1:128	52.1 (44.2 to 59.9)	60.8 (52.3 to 68.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at Year 1 in the ACWY1d and ACWY2d Groups

End point title	Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at Year 1 in the ACWY1d and ACWY2d Groups[7][8]

End point description:

GMTs of antibodies against each serogroup were assessed using rSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). rSBA titers are expressed as 1/dilution. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. Here "number of subjects analysed" signifies subjects evaluable for this endpoint. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 reporting groups.

End point type	Primary

End point timeframe:

At Year 1

Notes:

[7] - 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 analyses was not planned for this endpoint only descriptive data was planned.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	167	143		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
rSBA-MenA	62.7 (42.6 to 92.2)	76.6 (50.7 to 115.7)		
rSBA-MenC	16.2 (12.4 to 21.1)	21.2 (15.6 to 28.9)		
rSBA-MenW-135	57.2 (39.9 to 82.0)	123.1 (82.7 to 183.4)		
rSBA-MenY	76.8 (54.2 to 109.0)	112.3 (77.5 to 162.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at Year 3 in the ACWY1d and ACWY2d Groups

End point title	Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at Year 3 in the ACWY1d and ACWY2d Groups[9][10]

End point description:

Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with rSBA titers >=1:8 and >=1:128 against each serogroup at Year 3 after administration of MenACWY-TT are reported. ATP cohort for persistence Year 3 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. Here "number of subjects analysed" signifies subjects evaluable for this endpoint. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 reporting groups.

End point type	Primary

End point timeframe:

At Year 3

Notes:

[9] - 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 analyses was not planned for this endpoint only descriptive data was planned.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	147	121		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8	46.9 (38.7 to 55.3)	54.5 (45.2 to 63.6)		
rSBA-MenC: >=1:8	35.4 (27.7 to 43.7)	33.9 (25.5 to 43.0)		
rSBA-MenW-135: >=1:8	59.2 (50.8 to 67.2)	72.7 (63.9 to 80.4)		
rSBA-MenY: >=1:8	61.9 (53.5 to 69.8)	68.6 (59.5 to 76.7)		
rSBA-MenA: >=1:128	34.0 (26.4 to 42.3)	31.4 (23.3 to 40.5)		
rSBA-MenC: >=1:128	9.5 (5.3 to 15.5)	15.7 (9.7 to 23.4)		
rSBA-MenW-135: >=1:128	42.9 (34.7 to 51.3)	52.9 (43.6 to 62.0)		
rSBA-MenY: >=1:128	49.0 (40.7 to 57.3)	53.7 (44.4 to 62.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at Year 3 in the ACWY1d and ACWY2d Groups

End point title	Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at Year 3 in the ACWY1d and ACWY2d Groups[11][12]

End point description:

GMTs of antibodies against each serogroup were assessed using rSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). rSBA titers are expressed as 1/dilution. ATP cohort for persistence Year 3 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. Here "number of subjects analysed" signifies subjects evaluable for this endpoint. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 reporting groups.

End point type	Primary

End point timeframe:

At Year 3

Notes:

[11] - 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 analyses was not planned for this endpoint only descriptive data was planned.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	147	121		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
rSBA-MenA	29.7 (19.8 to 44.5)	28.5 (18.7 to 43.6)		
rSBA-MenC	9.8 (7.6 to 12.7)	11.5 (8.4 to 15.8)		
rSBA-MenW-135	42.5 (29.2 to 61.8)	92.9 (59.9 to 143.9)		
rSBA-MenY	58.0 (39.1 to 86.0)	75.1 (48.7 to 115.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at Year 5 in the ACWY1d and ACWY2d Groups

End point title	Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at Year 5 in the ACWY1d and ACWY2d Groups[13][14]

End point description:

Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135), Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with rSBA titers >=1:8 and >=1:128 against each serogroup at Year 5 after administration of MenACWY-TT are reported. ATP cohort for persistence Year 5 included all

subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint and 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 groups.

End point type	Primary

End point timeframe:

At Year 5

Notes:

[13] - 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 analyses was not planned for this endpoint only descriptive data was planned.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	117		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8 (n=133, 117)	58.6 (49.8 to 67.1)	65.8 (56.5 to 74.3)		
rSBA-MenC: >=1:8 (n=132, 116)	20.5 (13.9 to 28.3)	28.4 (20.5 to 37.6)		
rSBA-MenW-135: >=1:8 (n=133, 117)	44.4 (35.8 to 53.2)	50.4 (41.0 to 59.8)		
rSBA-MenY: >=1:8 (n=133, 117)	47.4 (38.7 to 56.2)	58.1 (48.6 to 67.2)		
rSBA-MenA: >=1:128 (n=133, 117)	43.6 (35.0 to 52.5)	53.0 (43.5 to 62.3)		
rSBA-MenC: >=1:128 (n=132, 116)	6.1 (2.7 to 11.6)	10.3 (5.5 to 17.4)		
rSBA-MenW-135: >=1:128 (n=133, 117)	32.3 (24.5 to 41.0)	39.3 (30.4 to 48.8)		
rSBA-MenY: >=1:128 (n=133, 117)	39.8 (31.5 to 48.7)	52.1 (42.7 to 61.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at Year 5 in the ACWY1d and ACWY2d Groups

End point title	Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at Year 5 in the ACWY1d and ACWY2d Groups[15][16]

End point description:

GMTs of antibodies against each serogroup were assessed using rSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). rSBA titers are expressed as 1/dilution. ATP cohort for persistence Year 5 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied

with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. Here "number of subjects analysed"=subjects evaluable for this endpoint and 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 groups.

End point type	Primary

End point timeframe:

At Year 5

Notes:

[15] - 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 analyses was not planned for this endpoint only descriptive data was planned.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	117		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
rSBA-MenA (n=133, 117)	46.8 (30.7 to 71.5)	69.9 (44.7 to 109.3)		
rSBA-MenC (n=132, 116)	6.6 (5.3 to 8.2)	8.5 (6.4 to 11.2)		
rSBA-MenW-135 (n=133, 117)	25.0 (16.7 to 37.6)	37.1 (23.3 to 59.0)		
rSBA-MenY (n=133, 117)	36.5 (23.6 to 56.2)	55.8 (35.7 to 87.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentrations (GMCs) of Antibodies for Each of the Anti-pneumococcal Serotypes at 1 Month After Administration of Prevnar 13 in the Co-ad and PCV-13 Groups

End point title	Geometric Mean Concentrations (GMCs) of Antibodies for Each of the Anti-pneumococcal Serotypes at 1 Month After Administration of Prevnar 13 in the Co-ad and PCV-13 Groups[17][18]

End point description:

GMCs for anti-pneumococcal antibodies (anti-1, anti-3, anti-4, anti-5, anti-6A, anti-6B, anti-7F, anti-9V, anti-14, anti-18C, anti-19A, anti-19F and anti-23F) were measured in microgram per millilitre (mcg/mL). ATP cohort for immunogenicity post dose 1 included all evaluable subjects who met eligibility criteria, complied with the procedures defined in the protocol and with no elimination criteria during the study from the ATP cohort for safety, received all study vaccines at Month 0, had assay results available for antibodies against at least one study vaccine antigen component at Visit 2 (Month 1), and had available blood sample at Visit 2 (Month 1) for PCV13 group. Here "number of subjects analysed" signifies subjects evaluable for this endpoint and 'number analysed' signifies subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for ACWY1d and ACWY2d reporting groups.

End point type	Primary

End point timeframe:

1 month after administration of Prevnar 13 (i.e. at Month 1)

Notes:

[17] - 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 analyses was not planned for this endpoint only descriptive data was planned.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	Co-ad Group	PCV13 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	172		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
anti-1 (n=162, 171)	2.94 (2.56 to 3.36)	2.62 (2.27 to 3.01)		
anti-3 (n=151, 162)	0.80 (0.69 to 0.91)	0.71 (0.62 to 0.81)		
anti-4 (n=163, 172)	2.46 (2.14 to 2.83)	1.96 (1.69 to 2.26)		
anti-5 (n=163, 172)	2.09 (1.84 to 2.37)	1.67 (1.46 to 1.91)		
anti-6A (n=163, 171)	8.59 (7.50 to 9.85)	7.28 (6.33 to 8.37)		
anti-6B (n=161, 171)	7.36 (6.33 to 8.55)	6.68 (5.70 to 7.83)		
anti-7F (n=163, 172)	5.14 (4.49 to 5.88)	4.81 (4.23 to 5.47)		
anti-9V (n=163, 172)	2.03 (1.78 to 2.30)	1.79 (1.59 to 2.03)		
anti-14 (n=161, 172)	13.1 (11.38 to 15.07)	11.94 (10.43 to 13.66)		
anti-18C (n=163, 172)	2.53 (2.19 to 2.92)	2.13 (1.84 to 2.47)		
anti-19A (n=162, 170)	9.60 (8.41 to 10.97)	8.62 (7.53 to 9.87)		
anti-19F (n=162, 172)	8.40 (7.33 to 9.62)	7.98 (6.96 to 9.15)		
anti-23F (n=161, 169)	5.33 (4.57 to 6.21)	4.47 (3.83 to 5.23)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Serum Bactericidal Assay Using Human Complement (hSBA) Titers >=1:4 and >=1:8 at 1 Month After Administration of 1 Dose of MenACWY-TT in the ACWY1d and ACWY2d Groups

End point title	Percentage of Subjects With Serum Bactericidal Assay Using Human Complement (hSBA) Titers >=1:4 and >=1:8 at 1 Month After Administration of 1 Dose of MenACWY-TT in the ACWY1d and ACWY2d Groups[19]

End point description:

Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135), Neisseria meningitidis serogroup Y

(MenY). Percentage of subjects with hSBA titers >=1:4 and >=1:8 against each serogroup at 1 month after administration of MenACWY-TT are reported. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint and 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 groups.

End point type	Secondary

End point timeframe:

1 month after administration of 1st dose of MenACWY-TT (i.e. at Month 1)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	70		
Units: percentage of subjects				
number (confidence interval 95%)				
hSBA-MenA: >=1:4 (n=74, 66)	95.9 (88.6 to 99.2)	97.0 (89.5 to 99.6)		
hSBA-MenC: >=1:4 (n=78, 70)	98.7 (93.1 to 100.0)	97.1 (90.1 to 99.7)		
hSBA-MenW-135: >=1:4 (n=72, 61)	62.5 (50.3 to 73.6)	68.9 (55.7 to 80.1)		
hSBA-MenY: >=1:4 (n=71, 56)	67.6 (55.5 to 78.2)	64.3 (50.4 to 76.6)		
hSBA-MenA: >=1:8 (n=74, 66)	95.9 (88.6 to 99.2)	97.0 (89.5 to 99.6)		
hSBA-MenC: >=1:8 (n=78, 70)	98.7 (93.1 to 100.0)	95.7 (88.0 to 99.1)		
hSBA-MenW-135: >=1:8 (n=72, 61)	62.5 (50.3 to 73.6)	68.9 (55.7 to 80.1)		
hSBA-MenY: >=1:8 (n=71, 56)	67.6 (55.5 to 78.2)	64.3 (50.4 to 76.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Titers >=1:4 and >=1:8 at 1 Month After Administration of 2 Doses of MenACWY-TT in the ACWY2d Group

End point title	Percentage of Subjects With hSBA Titers >=1:4 and >=1:8 at 1 Month After Administration of 2 Doses of MenACWY-TT in the ACWY2d Group[20]

End point description:

Serogroups:Neisseria meningitidis serogroup A (MenA),Neisseria meningitidis serogroup C (MenC),Neisseria meningitidis serogroup W-135 (MenW-135),Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with hSBA titers >=1:4 and >=1:8 against each serogroup at 1 month after administration of 2 doses of MenACWY-TT reported. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum

sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint. 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for ACWY1d, Co-ad and PCV13 groups.

End point type	Secondary

End point timeframe:

1 month after administration of 2nd dose of MenACWY-TT (i.e. at Month 3)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY2d Group			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: percentage of subjects				
number (confidence interval 95%)				
hSBA-MenA: >=1:4 (n= 66)	97.0 (89.5 to 99.6)			
hSBA-MenC: >=1:4 (n= 69)	100.0 (94.8 to 100.0)			
hSBA-MenW-135: >=1:4 (n= 70)	97.1 (90.1 to 99.7)			
hSBA-MenY: >=1:4 (n= 64)	95.3 (86.9 to 99.0)			
hSBA-MenA: >=1:8 (n= 66)	97.0 (89.5 to 99.6)			
hSBA-MenC: >=1:8 (n= 69)	100.0 (94.8 to 100.0)			
hSBA-MenW-135: >=1:8 (n= 70)	97.1 (90.1 to 99.7)			
hSBA-MenY: >=1:8 (n= 64)	95.3 (86.9 to 99.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) With hSBA for Each of the 4 Serogroups Following Vaccination at 1 Month After Administration of 1 Dose of MenACWY-TT in the ACWY1d and ACWY2d Groups

End point title	Geometric Mean Titers (GMTs) With hSBA for Each of the 4 Serogroups Following Vaccination at 1 Month After Administration of 1 Dose of MenACWY-TT in the ACWY1d and ACWY2d Groups[21]

End point description:

GMTs of antibodies against each serogroup were assessed using hSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). hSBA titers are expressed as 1/dilution. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint and 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 groups.

End point type	Secondary

End point timeframe:

1 month after administration of 1st dose of MenACWY-TT (i.e. at Month 1)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	70		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
hSBA-MenA (n=74, 66)	118.0 (86.8 to 160.5)	132.9 (98.1 to 180.1)		
hSBA-MenC (n=78, 70)	151.9 (104.8 to 220.4)	160.8 (109.8 to 235.5)		
hSBA-MenW-135 (n=72, 61)	27.5 (16.1 to 46.8)	26.2 (16.0 to 43.0)		
hSBA-MenY (n=71, 56)	41.2 (23.7 to 71.5)	31.9 (17.6 to 57.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) With hSBA for Each of the 4 Serogroups Following Vaccination at 1 Month After Administration of 2 Doses of MenACWY-TT in the ACWY2d Group

End point title	Geometric Mean Titers (GMTs) With hSBA for Each of the 4 Serogroups Following Vaccination at 1 Month After Administration of 2 Doses of MenACWY-TT in the ACWY2d Group[22]

End point description:

GMTs of antibodies against each serogroup were assessed using hSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). hSBA titers are expressed as 1/dilution. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint and ‘n’=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 groups.

End point type	Secondary

End point timeframe:

1 month after administration of 2nd dose of MenACWY-TT (i.e. at Month 3)

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY2d Group			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
hSBA-MenA (n= 66)	170.5 (126.2 to 230.2)			
hSBA-MenC (n= 69)	1753.3 (1278.7 to 2404.2)			
hSBA-MenW-135 (n= 70)	756.8 (550.1 to 1041.3)			
hSBA-MenY (n= 64)	513.0 (339.4 to 775.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at 1 Month After Administration of 1 Dose of MenACWY-TT in the PCV-13 Group

End point title	Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at 1 Month After Administration of 1 Dose of MenACWY-TT in the PCV-13 Group[23]

End point description:

Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with rSBA titers >=1:8 and >=1:128 against each serogroup at 1 month after administration of MenACWY-TT are reported. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. Here "number of subjects analysed" signifies subjects evaluable for this endpoint. Data for this endpoint was not planned to be collected and analysed for ACWY1d, ACWY2d and Co-ad reporting groups.

End point type	Secondary

End point timeframe:

1 month after administration of 1st dose of MenACWY-TT (i.e. at Month 3)

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	PCV13 Group			
Subject group type	Reporting group			
Number of subjects analysed	169			
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8	96.4 (92.4 to 98.7)			
rSBA-MenC: >=1:8	95.3 (90.9 to 97.9)			

rSBA-MenW-135: >=1:8	96.4 (92.4 to 98.7)			
rSBA-MenY: >=1:8	97.0 (93.2 to 99.0)			
rSBA-MenA: >=1:128	95.9 (91.7 to 98.3)			
rSBA-MenC: >=1:128	85.8 (79.6 to 90.7)			
rSBA-MenW-135: >=1:128	96.4 (92.4 to 98.7)			
rSBA-MenY: >=1:128	97.0 (93.2 to 99.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) With rSBA Titers for Each of the 4 Serogroups Following Vaccination at 1 Month After Administration of 1 Dose of MenACWY-TT in the PCV-13 Group

End point title	Geometric Mean Titers (GMTs) With rSBA Titers for Each of the 4 Serogroups Following Vaccination at 1 Month After Administration of 1 Dose of MenACWY-TT in the PCV-13 Group[24]

End point description:

GMTs of antibodies against each serogroup were assessed using rSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). rSBA titers are expressed as 1/dilution. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. Here "number of subjects analysed" signifies subjects evaluable for this endpoint. Data for this endpoint was not planned to be collected and analysed for ACWY1d, ACWY2d and Co-ad reporting groups.

End point type	Secondary

End point timeframe:

1 month after administration of 1st dose of MenACWY-TT (i.e. at Month 3)

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	PCV13 Group			
Subject group type	Reporting group			
Number of subjects analysed	169			
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
rSBA-MenA	1957.7 (1513.4 to 2532.3)			
rSBA-MenC	376.4 (284.7 to 497.6)			

rSBA-MenW-135	3490.5 (2643.3 to 4609.3)			
rSBA-MenY	1481.2 (1158.4 to 1893.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With rSBA Titers >=1:128 at 1 Month After Administration of 1 Dose of MenACWY-TT in the ACWY1d, ACWY2d and Co-ad Groups

End point title	Percentage of Subjects With rSBA Titers >=1:128 at 1 Month After Administration of 1 Dose of MenACWY-TT in the ACWY1d, ACWY2d and Co-ad Groups[25]

End point description:

Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with rSBA titers >=1:128 against each serogroup at 1 month after administration of MenACWY-TT are reported. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint and 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for PCV13 group.

End point type	Secondary

End point timeframe:

1 month after administration of 1st dose of MenACWY-TT (i.e. at Month 1)

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	180	158	178	
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA (n=180, 158, 178)	94.4 (90.0 to 97.3)	95.6 (91.1 to 98.2)	93.8 (89.2 to 96.9)	
rSBA-MenC (n=179, 157, 176)	85.5 (79.4 to 90.3)	85.4 (78.8 to 90.5)	88.1 (82.3 to 92.5)	
rSBA-MenW-135 (n=180, 158, 177)	95.0 (90.7 to 97.7)	94.3 (89.5 to 97.4)	92.7 (87.8 to 96.0)	
rSBA-MenY (n=180, 157, 177)	90.6 (85.3 to 94.4)	91.7 (86.3 to 95.5)	89.3 (83.7 to 93.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at 1 Month After Administration of 1 Dose of MenACWY-TT in ACWY1d, ACWY2d and Co-ad Groups

End point title	Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at 1 Month After Administration of 1 Dose of MenACWY-TT in ACWY1d, ACWY2d and Co-ad Groups[26]

End point description:

GMTs of antibodies against each serogroup were assessed using rSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). rSBA titers are expressed as 1/dilution. ATP cohort for persistence Year 1 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint and 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for PCV13 group.

End point type	Secondary

End point timeframe:

1 month after administration of 1st dose of MenACWY-TT (i.e. at Month 1)

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	180	158	178	
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
rSBA-MenA (n=180, 158, 178)	1437.0 (1118.3 to 1846.6)	1275.2 (970.5 to 1675.4)	1146.4 (867.9 to 1514.3)	
rSBA-MenC (n=179, 157, 176)	452.3 (345.6 to 591.9)	369.3 (280.9 to 485.5)	337.3 (263.8 to 431.1)	
rSBA-MenW-135 (n=180, 158, 177)	2120.2 (1601.0 to 2807.8)	2030.1 (1510.7 to 2728.2)	1550.9 (1137.4 to 2114.7)	
rSBA-MenY (n=180, 157, 177)	951.8 (705.0 to 1284.9)	933.3 (692.3 to 1258.3)	778.5 (566.2 to 1070.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Titers >=1:4 and >=1:8 at Year 1, 3 and 5 in the ACWY1d and ACWY2d Groups

End point title	Percentage of Subjects With hSBA Titers >=1:4 and >=1:8 at Year 1, 3 and 5 in the ACWY1d and ACWY2d Groups[27]

End point description:

Serogroups:Neisseria meningitidis serogroup A (MenA),Neisseria meningitidis serogroup C (MenC),Neisseria meningitidis serogroup W-135 (MenW-135),Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with hSBA titers >=1:4 and >=1:8 against each serogroup at Year 1, 3 and 5 after administration of MenACWY-TT reported. ATP cohort for persistence Year 1, 3 and 5 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint. 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 groups.

End point type	Secondary

End point timeframe:

At Year 1, Year 3, Year 5

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	72	65		
Units: percentage of subjects				
number (confidence interval 95%)				
hSBA-MenA: >=1:4 (Year 1) (n=70, 62)	37.1 (25.9 to 49.5)	35.5 (23.7 to 48.7)		
hSBA-MenC: >=1:4 (Year 1) (n=71, 63)	81.7 (70.7 to 89.9)	93.7 (84.5 to 98.2)		
hSBA-MenW-135: >=1:4 (Year 1) (n=72, 65)	95.8 (88.3 to 99.1)	98.5 (91.7 to 100.0)		
hSBA-MenY: >=1:4 (Year 1) (n=62, 58)	91.9 (82.2 to 97.3)	87.9 (76.7 to 95.0)		
hSBA-MenA: >=1:8 (Year 1) (n=70, 62)	35.7 (24.6 to 48.1)	35.5 (23.7 to 48.7)		
hSBA-MenC: >=1:8 (Year 1) (n=71, 63)	80.3 (69.1 to 88.8)	90.5 (80.4 to 96.4)		
hSBA-MenW-135: >=1:8 (Year 1) (n=72, 65)	95.8 (88.3 to 99.1)	98.5 (91.7 to 100.0)		
hSBA-MenY: >=1:8 (Year 1) (n=62, 58)	91.9 (82.2 to 97.3)	87.9 (76.7 to 95.0)		
hSBA-MenA: >=1:4 (Year 3) (n=55, 50)	36.4 (23.8 to 50.4)	36.0 (22.9 to 50.8)		
hSBA-MenC: >=1:4 (Year 3) (n=61, 56)	65.6 (52.3 to 77.3)	67.9 (54.0 to 79.7)		
hSBA-MenW-135: >=1:4 (Year 3) (n=67, 54)	71.6 (59.3 to 82.0)	87.0 (75.1 to 94.6)		
hSBA-MenY: >=1:4 (Year 3) (n=64, 52)	53.1 (40.2 to 65.7)	61.5 (47.0 to 74.7)		
hSBA-MenA: >=1:8 (Year 3) (n=55, 50)	36.4 (23.8 to 50.4)	36.0 (22.9 to 50.8)		
hSBA-MenC: >=1:8 (Year 3) (n=61, 56)	65.6 (52.3 to 77.3)	67.9 (54.0 to 79.7)		
hSBA-MenW-135: >=1:8 (Year 3) (n=67, 54)	71.6 (59.3 to 82.0)	87.0 (75.1 to 94.6)		
hSBA-MenY: >=1:8 (Year 3) (n=64, 52)	53.1 (40.2 to 65.7)	61.5 (47.0 to 74.7)		
hSBA-MenA: >=1:4 (Year 5) (n=61, 56)	27.9 (17.1 to 40.8)	17.9 (8.9 to 30.4)		

hSBA-MenC: >=1:4 (Year 5) (n=61, 59)	60.7 (47.3 to 72.9)	67.8 (54.4 to 79.4)		
hSBA-MenW-135: >=1:4 (Year 5) (n=56, 44)	58.9 (45.0 to 71.9)	63.6 (47.8 to 77.6)		
hSBA-MenY: >=1:4 (Year 5) (n=65, 48)	61.5 (48.6 to 73.3)	54.2 (39.2 to 68.6)		
hSBA-MenA: >=1:8 (Year 5) (n=61, 56)	27.9 (17.1 to 40.8)	17.9 (8.9 to 30.4)		
hSBA-MenC: >=1:8 (Year 5) (n=61, 59)	60.7 (47.3 to 72.9)	67.8 (54.4 to 79.4)		
hSBA-MenW-135: >=1:8 (Year 5) (n=56, 44)	58.9 (45.0 to 71.9)	63.6 (47.8 to 77.6)		
hSBA-MenY: >=1:8 (Year 5) (n=65, 48)	61.5 (48.6 to 73.3)	54.2 (39.2 to 68.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) With hSBA for Each of the 4 Serogroups Following Vaccination at Year 1, 3 and 5 in the ACWY1d and ACWY2d Groups

End point title	Geometric Mean Titers (GMTs) With hSBA for Each of the 4 Serogroups Following Vaccination at Year 1, 3 and 5 in the ACWY1d and ACWY2d Groups[28]

End point description:

GMTs of antibodies against each serogroup were assessed using hSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). hSBA titers are expressed as 1/dilution. ATP cohort for persistence Year 1, 3 and 5 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint and ‘n’=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for Co-ad and PCV13 groups.

End point type	Secondary

End point timeframe:

At Year 1, Year 3, Year 5

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	ACWY1d Group	ACWY2d Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	72	65		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
hSBA-MenA (Year 1) (n=70, 62)	6.1 (4.1 to 8.9)	6.4 (4.2 to 10.0)		
hSBA-MenC (Year 1) (n=71, 63)	35.2 (22.5 to 55.2)	73.4 (47.5 to 113.4)		
hSBA-MenW-135 (Year 1) (n=72, 65)	209.0 (149.9 to 291.4)	232.6 (168.3 to 321.4)		

hSBA-MenY (Year 1) (n=62, 58)	144.4 (97.2 to 214.5)	143.9 (88.5 to 233.8)		
hSBA-MenA (Year 3) (n=55, 50)	5.8 (3.8 to 8.9)	5.4 (3.6 to 8.0)		
hSBA-MenC (Year 3) (n=61, 56)	23.6 (13.9 to 40.2)	27.0 (15.6 to 46.8)		
hSBA-MenW-135 (Year 3) (n=67, 54)	30.5 (18.7 to 49.6)	55.5 (35.3 to 87.1)		
hSBA-MenY (Year 3) (n=64, 52)	17.3 (10.1 to 29.6)	24.1 (13.3 to 43.8)		
hSBA-MenA (Year 5) (n=61, 56)	4.4 (3.1 to 6.2)	3.1 (2.4 to 4.0)		
hSBA-MenC (Year 5) (n=61, 59)	18.1 (10.9 to 30.0)	29.4 (16.3 to 52.9)		
hSBA-MenW-135 (Year 5) (n=56, 44)	20.8 (11.6 to 37.1)	19.5 (10.7 to 35.2)		
hSBA-MenY (Year 5) (n=65, 48)	24.3 (14.3 to 41.1)	16.8 (9.0 to 31.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at Year 1, 3 and 5 in the Co-ad and PCV-13 Groups

End point title	Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 at Year 1, 3 and 5 in the Co-ad and PCV-13 Groups[29]

End point description:

Serogroups:Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC),Neisseria meningitidis serogroup W-135 (MenW-135),Neisseria meningitidis serogroup Y (MenY). Percentage of subjects with rSBA titers >=1:8 and >=1:128 against each serogroup at Year 1, 3 and 5 after administration of MenACWY-TT reported. ATP cohort for persistence Year 1, 3 and 5 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint. 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for ACWY1d and ACWY2d groups.

End point type	Secondary

End point timeframe:

At Year 1, Year 3, Year 5

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	Co-ad Group	PCV13 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	173	169		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8 (Year 1) (n=173, 169)	66.5 (58.9 to 73.5)	70.4 (62.9 to 77.2)		
rSBA-MenC: >=1:8 (Year 1) (n=171, 169)	42.7 (35.2 to 50.5)	50.3 (42.5 to 58.1)		

rSBA-MenW-135: >=1:8 (Year 1) (n=171, 169)	60.2 (52.5 to 67.6)	72.8 (65.4 to 79.3)		
rSBA-MenY: >=1:8 (Year 1) (n=173, 169)	67.1 (59.5 to 74.0)	80.5 (73.7 to 86.2)		
rSBA-MenA: >=1:128 (Year 1) (n=173, 169)	42.8 (35.3 to 50.5)	56.2 (48.4 to 63.8)		
rSBA-MenC: >=1:128 (Year 1) (n=171, 169)	15.8 (10.7 to 22.1)	20.1 (14.4 to 27.0)		
rSBA-MenW-135: >=1:128 (Year 1) (n=171, 169)	42.7 (35.2 to 50.5)	58.0 (50.2 to 65.5)		
rSBA-MenY: >=1:128 (Year 1) (n=173, 169)	53.8 (46.0 to 61.4)	69.2 (61.7 to 76.1)		
rSBA-MenA: >=1:8 (Year 3) (n=151, 132)	51.0 (42.7 to 59.2)	53.8 (44.9 to 62.5)		
rSBA-MenC: >=1:8 (Year 3) (n=151, 132)	28.5 (21.4 to 36.4)	31.8 (24.0 to 40.5)		
rSBA-MenW-135: >=1:8 (Year 3) (n=151, 132)	53.0 (44.7 to 61.1)	56.8 (47.9 to 65.4)		
rSBA-MenY: >=1:8 (Year 3) (n=151, 132)	62.9 (54.7 to 70.6)	73.5 (65.1 to 80.8)		
rSBA-MenA: >=1:128 (Year 3) (n=151, 132)	39.1 (31.2 to 47.3)	40.2 (31.7 to 49.0)		
rSBA-MenC: >=1:128 (Year 3) (n=151, 132)	14.6 (9.4 to 21.2)	10.6 (5.9 to 17.2)		
rSBA-MenW-135: >=1:128 (Year 3) (n=151, 132)	39.1 (31.2 to 47.3)	42.4 (33.9 to 51.3)		
rSBA-MenY: >=1:128 (Year 3) (n=151, 132)	53.0 (44.7 to 61.1)	59.8 (51.0 to 68.3)		
rSBA-MenA: >=1:8 (Year 5) (n=142, 129)	45.8 (37.4 to 54.3)	47.3 (38.4 to 56.3)		
rSBA-MenC: >=1:8 (Year 5) (n=142, 129)	23.9 (17.2 to 31.8)	19.4 (13.0 to 27.3)		
rSBA-MenW-135: >=1:8 (Year 5) (n=142, 129)	43.0 (34.7 to 51.5)	45.0 (36.2 to 54.0)		
rSBA-MenY: >=1:8 (Year 5) (n=142, 129)	52.8 (44.3 to 61.2)	55.8 (46.8 to 64.5)		
rSBA-MenA: >=1:128 (Year 5) (n=142, 129)	19.0 (12.9 to 26.4)	36.4 (28.1 to 45.4)		
rSBA-MenC: >=1:128 (Year 5) (n=142, 129)	12.0 (7.1 to 18.5)	7.8 (3.8 to 13.8)		
rSBA-MenW-135: >=1:128 (Year 5) (n=142, 129)	33.8 (26.1 to 42.2)	35.7 (27.4 to 44.6)		
rSBA-MenY: >=1:128 (Year 5) (n=142, 129)	42.3 (34.0 to 50.8)	48.1 (39.2 to 57.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at Year 1, 3 and 5 in the Co-ad and PCV-13 Groups

End point title	Geometric Mean Titers (GMTs) With rSBA for Each of the 4 Serogroups Following Vaccination at Year 1, 3 and 5 in the Co-ad and PCV-13 Groups[30]

End point description:

GMTs of antibodies against each serogroup were assessed using rSBA. Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). rSBA titers are expressed

as 1/dilution. ATP cohort for persistence Year 1, 3 and 5 included all subjects who met eligibility criteria, received complete primary vaccination series, had assay results available for at least 1 antigen tested, complied with procedures and intervals in protocol, did not present medical condition, received product or were non-compliant with protocol-defined serum sampling windows or lack of availability of immunogenicity results at the previous time point. "Number of subjects analysed"=subjects evaluable for this endpoint and 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for ACWY1d and ACWY2d groups.

End point type	Secondary

End point timeframe:

At Year 1, Year 3, Year 5

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	Co-ad Group	PCV13 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	173	169		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
rSBA-MenA (Year 1) (n=173, 169)	59.5 (40.7 to 87.2)	119.4 (79.5 to 179.3)		
rSBA-MenC (Year 1) (n=171, 169)	12.6 (10.0 to 16.0)	16.0 (12.2 to 20.9)		
rSBA-MenW-135 (Year 1) (n=171, 169)	52.0 (35.5 to 76.4)	109.5 (75.0 to 160.0)		
rSBA-MenY (Year 1) (n=173, 169)	70.7 (49.0 to 102.1)	169.2 (119.2 to 240.1)		
rSBA-MenA (Year 3) (n=151, 132)	38.6 (25.4 to 58.8)	42.3 (27.2 to 65.6)		
rSBA-MenC (Year 3) (n=151, 132)	9.1 (7.1 to 11.6)	9.3 (7.1 to 12.1)		
rSBA-MenW-135 (Year 3) (n=151, 132)	34.4 (23.4 to 50.6)	44.5 (28.9 to 68.7)		
rSBA-MenY (Year 3) (n=151, 132)	67.6 (45.6 to 100.3)	106.0 (70.2 to 160.0)		
rSBA-MenA (Year 5) (n=142, 129)	15.4 (11.1 to 21.3)	28.3 (18.5 to 43.2)		
rSBA-MenC (Year 5) (n=142, 129)	7.9 (6.2 to 10.0)	7.0 (5.5 to 8.8)		
rSBA-MenW-135 (Year 5) (n=142, 129)	26.2 (17.6 to 39.0)	31.7 (20.2 to 49.6)		
rSBA-MenY (Year 5) (n=142, 129)	43.3 (28.3 to 66.2)	53.9 (34.5 to 84.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Concentrations >=0.15 mcg/mL, >=0.26 mcg/mL and >=0.35 mcg/mL for Each of the Anti-pneumococcal Serotypes at 1 Month After Administration of Prevnar 13 in the Co-ad and PCV-13 Groups

End point title	Percentage of Subjects With Antibody Concentrations >=0.15 mcg/mL, >=0.26 mcg/mL and >=0.35 mcg/mL for Each of the

	Anti-pneumococcal Serotypes at 1 Month After Administration of Prevnar 13 in the Co-ad and PCV-13 Groups[31]

End point description:

Antibody concentrations determined for anti-pneumococcal antibodies:anti-1,anti-3,anti-4,anti-5,anti-6A,anti-6B, anti-7F, anti-9V, anti-14, anti-18C, anti-19A, anti-19F, anti-23F. Percentage of subjects with antibody concentrations >=0.15 mcg/mL, >=0.26 mcg/mL and >=0.35 mcg/mL against each serogroup at 1 month after administration of Prevnar 13 reported. ATP cohort for immunogenicity post dose 1: all evaluable subjects who met eligibility criteria, complied with procedures defined in protocol with no elimination criteria during study from ATP cohort for safety, received all study vaccines at Month 0, had assay results available for antibodies against at least 1 study vaccine antigen component at Visit 2, those with available blood sample at Visit 2 for PCV13 group. "Number of subjects analysed"=subjects evaluable for this endpoint. 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for ACWY1d and ACWY2d groups.

End point type	Secondary

End point timeframe:

1 month after administration of Prevnar 13 (i.e. at Month 1)

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	Co-ad Group	PCV13 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	172		
Units: percentage of subjects				
number (confidence interval 95%)				
anti-1 (>=0.15 mcg/mL) (n=162, 171)	100 (97.7 to 100)	100 (97.9 to 100)		
anti-3 (>=0.15 mcg/mL) (n=151, 162)	99.3 (96.4 to 100)	97.5 (93.8 to 99.3)		
anti-4 (>=0.15 mcg/mL) (n=163, 172)	100 (97.8 to 100)	99.4 (96.8 to 100)		
anti-5 (>=0.15 mcg/mL) (n=163, 172)	100 (97.8 to 100)	100 (97.9 to 100)		
anti-6A (>=0.15 mcg/mL) (n=163, 171)	100 (97.8 to 100)	100 (97.9 to 100)		
anti-6B (>=0.15 mcg/mL) (n=161, 171)	100 (97.7 to 100)	99.4 (96.8 to 100)		
anti-7F (>=0.15 mcg/mL) (n=163, 172)	100 (97.8 to 100)	100 (97.9 to 100)		
anti-9V (>=0.15 mcg/mL) (n=163, 172)	99.4 (96.6 to 100)	100 (97.9 to 100)		
anti-14 (>=0.15 mcg/mL) (n=161, 172)	100 (97.7 to 100)	99.4 (96.8 to 100)		
anti-18C (>=0.15 mcg/mL) (n=163, 172)	100 (97.8 to 100)	100 (97.9 to 100)		
anti-19A (>=0.15 mcg/mL) (n=162, 170)	100 (97.7 to 100)	100 (97.9 to 100)		
anti-19F (>=0.15 mcg/mL) (n=162, 172)	100 (97.7 to 100)	100 (97.9 to 100)		
anti-23F (>=0.15 mcg/mL) (n=161, 169)	100 (97.7 to 100)	100 (97.8 to 100)		
anti-1 (>=0.26 mcg/mL) (n=162, 171)	99.4 (96.6 to 100)	99.4 (96.8 to 100)		
anti-3 (>=0.26 mcg/mL) (n=151, 162)	94.0 (89.0 to 97.2)	88.3 (82.3 to 92.8)		
anti-4 (>=0.26 mcg/mL) (n=163, 172)	98.8 (95.6 to 99.9)	98.3 (95.0 to 99.6)		

anti-5 (>=0.26 mcg/mL) (n=163, 172)	99.4 (96.6 to 100)	98.8 (95.9 to 99.9)		
anti-6A (>=0.26 mcg/mL) (n=163, 171)	100 (97.8 to 100)	100 (97.9 to 100)		
anti-6B (>=0.26 mcg/mL) (n=161, 171)	100 (97.7 to 100)	99.4 (96.8 to 100)		
anti-7F (>=0.26 mcg/mL) (n=163, 172)	100 (97.8 to 100)	100 (97.9 to 100)		
anti-9V (>=0.26 mcg/mL) (n=163, 172)	99.4 (96.6 to 100)	98.8 (95.9 to 99.9)		
anti-14 (>=0.26 mcg/mL) (n=161, 172)	100 (97.7 to 100)	99.4 (96.8 to 100)		
anti-18C (>=0.26 mcg/mL) (n=163, 172)	98.8 (95.6 to 99.9)	99.4 (96.8 to 100)		
anti-19A (>=0.26 mcg/mL) (n=162, 170)	100 (97.7 to 100)	100 (97.9 to 100)		
anti-19F (>=0.26 mcg/mL) (n=162, 172)	100 (97.7 to 100)	100 (97.9 to 100)		
anti-23F (>=0.26 mcg/mL) (n=161, 169)	99.4 (96.6 to 100)	99.4 (96.7 to 100)		
anti-1 (>=0.35 mcg/mL) (n=162, 171)	99.4 (96.6 to 100)	98.2 (95.0 to 99.6)		
anti-3 (>=0.35 mcg/mL) (n=151, 162)	83.4 (76.5 to 89.0)	79.0 (71.9 to 85.0)		
anti-4 (>=0.35 mcg/mL) (n=163, 172)	96.9 (93.0 to 99.0)	97.1 (93.3 to 99.0)		
anti-5 (>=0.35 mcg/mL) (n=163, 172)	98.8 (95.6 to 99.9)	94.8 (90.3 to 97.6)		
anti-6A (>=0.35 mcg/mL) (n=163, 171)	99.4 (96.6 to 100)	100 (97.9 to 100)		
anti-6B (>=0.35 mcg/mL) (n=161, 171)	99.4 (96.6 to 100)	99.4 (96.8 to 100)		
anti-7F (>=0.35 mcg/mL) (n=163, 172)	99.4 (96.6 to 100)	100 (97.9 to 100)		
anti-9V (>=0.35 mcg/mL) (n=163, 172)	99.4 (96.6 to 100)	97.7 (94.2 to 99.4)		
anti-14 (>=0.35 mcg/mL) (n=161, 172)	100 (97.7 to 100)	99.4 (96.8 to 100)		
anti-18C (>=0.35 mcg/mL) (n=163, 172)	98.8 (95.6 to 99.9)	99.4 (96.8 to 100)		
anti-19A (>=0.35 mcg/mL) (n=162, 170)	100 (97.7 to 100)	100 (97.9 to 100)		
anti-19F (>=0.35 mcg/mL) (n=162, 172)	100 (97.7 to 100)	100 (97.9 to 100)		
anti-23F (>=0.35 mcg/mL) (n=161, 169)	99.4 (96.6 to 100)	99.4 (96.7 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Opsonophagocytic Activity (OPA) Titers >=1:8 for Each of the Anti-pneumococcal Serotypes at 1 Month After Administration of Prevnar 13 in the Co-ad and PCV-13 Groups

End point title	Percentage of Subjects With Opsonophagocytic Activity (OPA) Titers >=1:8 for Each of the Anti-pneumococcal Serotypes at 1 Month After Administration of Prevnar 13 in the Co-ad and PCV-13 Groups[32]

End point description:

OPA titers were determined for anti-pneumococcal serotypes: OPSONO-1,OPSONO-3,OPSONO-4,OPSONO-5, OPSONO-6A, OPSONO-6B, OPSONO-7F, OPSONO-9V, OPSONO-14, OPSONO-18C, OPSONO-19A, OPSONO-19F, OPSONO-23F. Percentage of subjects with OPA titers >=1:8 against each serogroup at 1 month after administration of Prevnar 13 are reported. ATP cohort for immunogenicity post dose 1: all evaluable subjects who met eligibility criteria, complied with the procedures defined in the protocol and with no elimination criteria during the study from the ATP cohort for safety, received all study vaccines at Month 0, had assay results available for antibodies against at least one study vaccine antigen component at Visit 2, those with available blood sample at Visit 2 for PCV13 group. "Number of subjects analysed"=subjects evaluable for this endpoint. 'n'=subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for ACWY1d and ACWY2d groups.

End point type	Secondary

End point timeframe:

1 month after administration of Prevnar 13 (i.e. at Month 1)

Notes:

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	Co-ad Group	PCV13 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	81	88		
Units: percentage of subjects				
number (confidence interval 95%)				
OPSONO-1 (n=81, 86)	93.8 (86.2 to 98.0)	90.7 (82.5 to 95.9)		
OPSONO-3 (n=76, 80)	98.7 (92.9 to 100)	100 (95.5 to 100)		
OPSONO-4 (n=77, 80)	100 (95.3 to 100)	100 (95.5 to 100)		
OPSONO-5 (n=81, 87)	100 (95.5 to 100)	100 (95.8 to 100)		
OPSONO-6A (n=81, 88)	100 (95.5 to 100)	100 (95.9 to 100)		
OPSONO-6B (n=75, 78)	100 (95.2 to 100)	100 (95.4 to 100)		
OPSONO-7F (n=81, 87)	100 (95.5 to 100)	100 (95.8 to 100)		
OPSONO-9V (n=81, 88)	100 (95.5 to 100)	100 (95.9 to 100)		
OPSONO-14 (n=73, 78)	100 (95.1 to 100)	100 (95.4 to 100)		
OPSONO-18C (n=81, 88)	100 (95.5 to 100)	100 (95.9 to 100)		
OPSONO-19A (n=81, 88)	100 (95.5 to 100)	100 (95.9 to 100)		
OPSONO-19F (n=81, 88)	98.8 (93.3 to 100)	100 (95.9 to 100)		
OPSONO-23F (n=77, 80)	98.7 (93.0 to 100)	98.8 (93.2 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) With OPA for Each of the Anti-pneumococcal Serotypes at 1 Month After Administration of Prevnar 13 in the Co-ad and PCV-13 Groups

End point title	Geometric Mean Titers (GMTs) With OPA for Each of the Anti-pneumococcal Serotypes at 1 Month After Administration of Prevnar 13 in the Co-ad and PCV-13 Groups[33]

End point description:

OPA titers were determined for anti-pneumococcal serotypes: OPSONO-1, OPSONO-3, OPSONO-4, OPSONO-5, OPSONO-6A, OPSONO-6B, OPSONO-7F, OPSONO-9V, OPSONO-14, OPSONO-18C, OPSONO-19A, OPSONO-19F and OPSONO-23F. OPA titers are expressed as 1/dilution. ATP cohort for immunogenicity post dose 1 included all evaluable subjects who met eligibility criteria, complied with the procedures defined in the protocol and with no elimination criteria during the study from the ATP cohort for safety, received all study vaccines at Month 0, had assay results available for antibodies against at least one study vaccine antigen component at Visit 2, those with available blood sample at Visit 2 for PCV13 group. Here "number of subjects analysed" signifies subjects evaluable for this endpoint and 'number analysed' signifies subjects evaluable for each specified category. Data for this endpoint was not planned to be collected and analysed for ACWY1d and ACWY2d reporting groups.

End point type	Secondary

End point timeframe:

1 month after administration of Prevnar 13 (i.e. at Month 1)

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses was not planned for this endpoint only descriptive data was planned.

End point values	Co-ad Group	PCV13 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	81	88		
Units: titers				
geometric mean (confidence interval 95%)				
OPSONO-1 (n=81, 86)	116.1 (83.8 to 160.7)	106.1 (77.0 to 146.2)		
OPSONO-3 (n=76, 80)	137.6 (106.4 to 178.0)	122.0 (100.6 to 147.9)		
OPSONO-4 (n=77, 80)	2194.8 (1660.0 to 2901.9)	2210.1 (1735.0 to 2815.2)		
OPSONO-5 (n=81, 87)	452.3 (360.4 to 567.5)	404.6 (319.1 to 512.9)		
OPSONO-6A (n=81, 88)	10177.2 (7784.7 to 13305.1)	7354.2 (5707.4 to 9476.1)		
OPSONO-6B (n=75, 78)	4952.3 (3734.4 to 6567.4)	3881.5 (3055.8 to 4930.2)		
OPSONO-7F (n=81, 87)	8957.4 (7306.4 to 10981.5)	8526.5 (6926.2 to 10496.7)		
OPSONO-9V (n=81, 88)	3375.5 (2539.6 to 4486.6)	2332.3 (1766.1 to 3080.1)		
OPSONO-14 (n=73, 78)	3443.7 (2453.5 to 4833.5)	3157.8 (2445.4 to 4077.8)		
OPSONO-18C (n=81, 88)	3881.0 (2947.2 to 5110.7)	3289.8 (2513.7 to 4305.5)		

OPSONO-19A (n=81, 88)	3362.5 (2639.6 to 4283.4)	2494.3 (1986.7 to 3131.6)		
OPSONO-19F (n=81, 88)	1795.5 (1305.6 to 2469.2)	1647.6 (1287.6 to 2108.3)		
OPSONO-23F (n=77, 80)	7755.7 (5450.9 to 11034.9)	5677.4 (4255.0 to 7575.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Local Reactions Within 4 Days Post Each Vaccination

End point title	Number of Subjects With Solicited Local Reactions Within 4 Days Post Each Vaccination

End point description:

Solicited local reactions included pain, redness and swelling. Here, '99999' in the number analysed field signifies that no vaccine was administered in the specified group for the specified category. The total vaccinated cohort (TVC) included all subjects vaccinated with at least 1 dose of study vaccine. The analysis was performed per vaccine actually administered at Dose 1. Here "number of subjects analysed" signifies subjects evaluable for this endpoint and ‘number analysed’ signifies subjects evaluable for each specified category.

End point type	Secondary

End point timeframe:

Within 4 days post each vaccination (vaccination 1 [at Month 0] and vaccination 2 [at Month 2])

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	PCV13 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	196	197	197
Units: subjects				
Pain:Post MenACWY-TT Dose 1 (n=199, 195, 197, 0)	52	64	72	99999
Pain:Post Prevenar 13 Dose 1 (n=0, 0, 196, 196)	99999	99999	85	72
Pain:Post MenACWY-TT Dose 2 (n=0, 189, 0, 191)	99999	58	99999	53
Redness:Post MenACWY-TT Dose 1 (n=199,195,197,0)	68	73	73	99999
Redness:Post Prevenar 13 Dose 1 (n=0,0,196,196)	99999	99999	87	90
Redness:Post MenACWY-TT Dose 2 (n=0,189,0,191)	99999	64	99999	66
Swelling:Post MenACWY-TT Dose 1 (n=199,195,197,0)	35	45	43	99999
Swelling:Post Prevenar 13 Dose 1 (n=0,0,196,196)	99999	99999	69	63
Swelling:Post MenACWY-TT Dose 2 (n=0,189,0,191)	99999	34	99999	30

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited General Reactions Within 4 Days Post Each Vaccination

End point title	Number of Subjects With Solicited General Reactions Within 4 Days Post Each Vaccination

End point description:

Solicited general reactions included drowsiness, irritability/fussiness, loss of appetite and fever. Here, '99999' in the number analysed field signifies that no vaccine was administered in the specified group for the specified category. Post dose 1 for ACWY1d and Co-ad group included reactions occurred after dosing of both MenACWY-TT and Prevenar 13 for Co-ad group and data was collected and summarised collectively. The total vaccinated cohort (TVC) included all subjects vaccinated with at least 1 dose of study vaccine. The analysis was performed per vaccine actually administered at Dose 1. Here "number of subjects analysed" signifies subjects evaluable for this endpoint and 'number analysed' signifies subjects evaluable for each specified category.

End point type	Secondary

End point timeframe:

Within 4 days post each vaccination (vaccination 1 [Dose 1] and vaccination 2 [Dose 2])

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	PCV13 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	196	197	197
Units: subjects				
Drowsiness:Post Dose 1 (n=199,195,197,196)	62	73	85	72
Drowsiness:Post Dose 2 (n=0,189,0,191)	99999	60	99999	50
Irritable/Fussiness:PostDose1(n=199,195,197,196)	89	93	107	85
Irritability/Fussiness:Post Dose 2(n=0,189,0,191)	99999	76	99999	67
Loss of Appetite:Post Dose 1 (n=199,195,197,196)	56	60	54	58
Loss of Appetite:Post Dose 2 (n=0,189,0,191)	99999	45	99999	47
Fever:Post Dose 1 (n=199,195,197,196)	26	25	34	43
Fever:Post Dose 2 (n=0,189,0,191)	99999	23	99999	25

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Unsolicited Adverse Events Within 31 Days Post any Study Vaccination, Classified According to Medical Dictionary for Regulatory Activities (MedDRA)

End point title	Number of Subjects With Unsolicited Adverse Events Within 31 Days Post any Study Vaccination, Classified According to Medical Dictionary for Regulatory Activities (MedDRA)

End point description:

An adverse event was any untoward medical occurrence in a subject, temporarily associated with the use of a medicinal product, whether or not considered related to the medicinal product. An unsolicited adverse event was an observed adverse event that did not fulfill the conditions prelisted in the case report book (CRB) in terms of symptom and/or onset post-vaccination. The total vaccinated cohort (TVC) included all subjects vaccinated with at least 1 dose of study vaccine. The analysis was performed per vaccine actually administered at Dose 1.

End point type	Secondary

End point timeframe:

Within 31 days post any vaccination

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	PCV13 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	197	201	201
Units: subjects	11	15	11	11

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Adverse Events from Month 0 to Month 9

End point title	Number of Subjects With Serious Adverse Events from Month 0 to Month 9

End point description:

An adverse event was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Serious adverse event was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. The total vaccinated cohort (TVC) included all subjects vaccinated with at least 1 dose of study vaccine. The analysis was performed per vaccine actually administered at Dose 1.

End point type	Secondary

End point timeframe:

Month 0 to Month 9

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	PCV13 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	197	201	201
Units: subjects	8	6	10	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Adverse Events Related to Study Vaccination From First Dose of Study Drug up to End of Study

End point title	Number of Subjects With Serious Adverse Events Related to Study Vaccination From First Dose of Study Drug up to End of Study

End point description:

An adverse event was any untoward medical occurrence in a subject who received study drug. Serious adverse event was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Related adverse events were those adverse events who were related to the vaccination as judged by the investigator. The total vaccinated cohort (TVC) included all subjects vaccinated with at least 1 dose of study vaccine. The analysis was performed per vaccine actually administered at Dose 1.

End point type	Secondary

End point timeframe:

Baseline up to end of study (up to 5 years)

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	PCV13 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	197	201	201
Units: subjects	0	2	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Any New Onset of Chronic Illnesses (NOCIs) from Month 0 to Month 9

End point title	Number of Subjects With Any New Onset of Chronic Illnesses (NOCIs) from Month 0 to Month 9

End point description:

New onset chronic illness included autoimmune disorders, asthma, type I diabetes and allergies. The total vaccinated cohort (TVC) included all subjects vaccinated with at least 1 dose of study vaccine. The analysis was performed per vaccine actually administered at Dose 1.

End point type	Secondary

End point timeframe:

Month 0 to Month 9

End point values	ACWY1d Group	ACWY2d Group	Co-ad Group	PCV13 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	197	201	201
Units: subjects	2	3	1	5

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events data were collected from Baseline up to end of study (up to 5 years). Solicited local and general reactions was collected within 4 days post vaccination.

Adverse event reporting additional description:

Same event may appear as both an adverse event and serious adverse events. However, what is presented are distinct events. An event may be categorised as serious in one subject and as non-serious in another, or a subject may have experienced both a serious and non-serious event.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	ACWY1d Group

Reporting group description:

Subjects received single dose of MenACWY-TT vaccine administered intramuscularly at Month 0.

Reporting group title	Co-ad Group

Reporting group description:

Subjects received single dose of MenACWY-TT vaccine and single dose of Prevnar 13 administered intramuscularly at Month 0.

Reporting group title	PCV13 Group

Reporting group description:

Subjects received single dose of Prevnar 13 at Month 0 and single dose of MenACWY-TT administered intramuscularly at Month 2.

Reporting group title	ACWY2d Group

Reporting group description:

Subjects received two doses of MenACWY-TT vaccine administered intramuscularly at Month 0 and Month 2.

Serious adverse events	ACWY1d Group	Co-ad Group	PCV13 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 203 (5.91%)	13 / 201 (6.47%)	16 / 201 (7.96%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Burns first degree			

subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (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
Petroleum distillate poisoning			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (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
Neutropenia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (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
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			

subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aspiration			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Asthma			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 203 (0.00%)	2 / 201 (1.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 203 (0.49%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 203 (0.49%)	2 / 201 (1.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			

subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myringitis			

subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 203 (0.49%)	3 / 201 (1.49%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal scalded skin syndrome			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			

subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 203 (0.00%)	3 / 201 (1.49%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Marasmus			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ACWY2d Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 197 (5.58%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm			

subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Burns first degree			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burns second degree			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Petroleum distillate poisoning			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin laceration			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Soft tissue injury			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			

Febrile convulsion			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukopenia			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			

subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asphyxia				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspiration				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Dermatitis allergic				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess limb				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchiolitis				
subjects affected / exposed	2 / 197 (1.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchitis				

subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis viral				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Croup infectious				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	2 / 197 (1.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis rotavirus				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis salmonella				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngitis				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis aseptic				

subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myringitis			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	3 / 197 (1.52%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumonia pneumococcal			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal scalded skin syndrome			

subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Marasmus			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	ACWY1d Group	Co-ad Group	PCV13 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	199 / 203 (98.03%)	197 / 201 (98.01%)	197 / 201 (98.01%)
General disorders and administration site conditions			
Crying			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	1	0	1
Gait disturbance			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Injection site bruising			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Injection site mass			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Malaise			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	12 / 203 (5.91%)	12 / 201 (5.97%)	13 / 201 (6.47%)
occurrences (all)	12	12	13
Swelling face			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Vaccination site bruising			
subjects affected / exposed	1 / 203 (0.49%)	1 / 201 (0.50%)	2 / 201 (1.00%)
occurrences (all)	1	1	2
Vaccination site pain			

subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Redness	Additional description: Number of subjects evaluable for this local reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[1]	68 / 199 (34.17%)	94 / 197 (47.72%)	108 / 197 (54.82%)
occurrences (all)	68	94	108
Pain	Additional description: Number of subjects evaluable for this local reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	52 / 199 (26.13%)	94 / 197 (47.72%)	91 / 197 (46.19%)
occurrences (all)	52	94	91
Swelling	Additional description: Number of subjects evaluable for this local reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[3]	35 / 199 (17.59%)	75 / 197 (38.07%)	73 / 197 (37.06%)
occurrences (all)	35	75	73
Irritability/Fussiness	Additional description: Number of subjects evaluable for this general reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[4]	89 / 199 (44.72%)	107 / 197 (54.31%)	108 / 197 (54.82%)
occurrences (all)	89	107	108
Drowsiness	Additional description: Number of subjects evaluable for this general reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[5]	62 / 199 (31.16%)	85 / 197 (43.15%)	89 / 197 (45.18%)
occurrences (all)	62	85	89
Loss Of Appetite	Additional description: Number of subjects evaluable for this general reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[6]	56 / 199 (28.14%)	54 / 197 (27.41%)	83 / 197 (42.13%)
occurrences (all)	56	54	83
Temperature/(Rectal) (°C)	Additional description: Number of subjects evaluable for this general reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[7]	26 / 199 (13.07%)	34 / 197 (17.26%)	63 / 197 (31.98%)
occurrences (all)	26	34	63
Immune system disorders			
Food allergy			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Hypersensitivity			

subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Immunisation reaction			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Balanoposthitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Genital rash			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Vulvovaginal adhesion			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Vulvovaginal pruritus			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	2 / 203 (0.99%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	2	0	1
Catarrh			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	13 / 203 (6.40%)	8 / 201 (3.98%)	12 / 201 (5.97%)
occurrences (all)	13	8	12
Epistaxis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Nasal congestion			

subjects affected / exposed	0 / 203 (0.00%)	2 / 201 (1.00%)	6 / 201 (2.99%)
occurrences (all)	0	2	6
Nasal disorder			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Nasal mucosal discolouration			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Respiratory symptom			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Respiratory disorder			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	6 / 203 (2.96%)	6 / 201 (2.99%)	7 / 201 (3.48%)
occurrences (all)	6	6	7
Wheezing			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Psychiatric disorders			
Autism spectrum disorder			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Fear			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	0 / 203 (0.00%)	5 / 201 (2.49%)	3 / 201 (1.49%)
occurrences (all)	0	5	3

Insomnia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	1	0	2
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	1	0	1
Soft tissue injury			

subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	1 / 203 (0.49%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	1	1	0
Tibia fracture			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Febrile convulsion			
subjects affected / exposed	3 / 203 (1.48%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	3	0	1
Poor quality sleep			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	1	0	1
Somnolence			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 203 (0.49%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	1	1	0
Ear and labyrinth disorders			

Ear disorder			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Corneal erosion			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Eye inflammation			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Abnormal faeces			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Aphthous ulcer			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	1	0	1
Coeliac disease			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	7 / 203 (3.45%)	9 / 201 (4.48%)	23 / 201 (11.44%)
occurrences (all)	7	9	23
Dyspepsia			

subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Faeces soft			
subjects affected / exposed	1 / 203 (0.49%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	1	1	0
Gastritis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	1	0	1
Stomatitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Teething			
subjects affected / exposed	7 / 203 (3.45%)	12 / 201 (5.97%)	18 / 201 (8.96%)
occurrences (all)	7	12	18
Tooth disorder			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	6 / 203 (2.96%)	4 / 201 (1.99%)	7 / 201 (3.48%)
occurrences (all)	6	4	7
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2

Dermatitis contact			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Eczema			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	5 / 201 (2.49%)
occurrences (all)	1	0	5
Dermatitis diaper			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	5 / 201 (2.49%)
occurrences (all)	0	0	5
Intertrigo			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Miliaria			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	5 / 203 (2.46%)	5 / 201 (2.49%)	4 / 201 (1.99%)
occurrences (all)	5	5	4
Petechiae			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Rash macular			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	1	0	2
Rash maculo-papular			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Rash morbilliform			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1

Urticaria			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 203 (0.49%)	2 / 201 (1.00%)	7 / 201 (3.48%)
occurrences (all)	1	2	7
Bronchitis			
subjects affected / exposed	2 / 203 (0.99%)	1 / 201 (0.50%)	4 / 201 (1.99%)
occurrences (all)	2	1	4
Conjunctivitis			
subjects affected / exposed	2 / 203 (0.99%)	4 / 201 (1.99%)	9 / 201 (4.48%)
occurrences (all)	2	4	9
Coxsackie viral infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	1	0	1
Croup infectious			
subjects affected / exposed	0 / 203 (0.00%)	2 / 201 (1.00%)	3 / 201 (1.49%)
occurrences (all)	0	2	3
Cystitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	1 / 203 (0.49%)	1 / 201 (0.50%)	3 / 201 (1.49%)
occurrences (all)	1	1	3
Erythema infectiosum			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Exanthema subitum			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Eye infection			

subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Eyelid infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Fungal infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 203 (0.49%)	2 / 201 (1.00%)	6 / 201 (2.99%)
occurrences (all)	1	2	6
Gastrointestinal bacterial infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 203 (0.49%)	6 / 201 (2.99%)	4 / 201 (1.99%)
occurrences (all)	1	6	4
Herpangina			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Infected bite			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 203 (0.49%)	4 / 201 (1.99%)	2 / 201 (1.00%)
occurrences (all)	1	4	2
Laryngitis			

subjects affected / exposed	1 / 203 (0.49%)	1 / 201 (0.50%)	2 / 201 (1.00%)
occurrences (all)	1	1	2
Lower respiratory tract infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	1	0	2
Measles			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	9 / 203 (4.43%)	11 / 201 (5.47%)	15 / 201 (7.46%)
occurrences (all)	9	11	15
Oral candidiasis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	3 / 203 (1.48%)	4 / 201 (1.99%)	11 / 201 (5.47%)
occurrences (all)	3	4	11
Otitis media acute			
subjects affected / exposed	0 / 203 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences (all)	0	1	0
Otosalpingitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	3 / 203 (1.48%)	2 / 201 (1.00%)	2 / 201 (1.00%)
occurrences (all)	3	2	2
Pharyngotonsillitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Pneumonia			

subjects affected / exposed	1 / 203 (0.49%)	2 / 201 (1.00%)	1 / 201 (0.50%)
occurrences (all)	1	2	1
Pulmonary tuberculosis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	4 / 203 (1.97%)	3 / 201 (1.49%)	4 / 201 (1.99%)
occurrences (all)	4	3	4
Roseola			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	2 / 201 (1.00%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Skin bacterial infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Staphylococcal infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	2 / 203 (0.99%)	1 / 201 (0.50%)	2 / 201 (1.00%)
occurrences (all)	2	1	2
Upper respiratory tract infection			
subjects affected / exposed	12 / 203 (5.91%)	15 / 201 (7.46%)	24 / 201 (11.94%)
occurrences (all)	12	15	24
Urinary tract infection			

subjects affected / exposed	1 / 203 (0.49%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	1	0	0
Varicella			
subjects affected / exposed	2 / 203 (0.99%)	1 / 201 (0.50%)	2 / 201 (1.00%)
occurrences (all)	2	1	2
Viral infection			
subjects affected / exposed	6 / 203 (2.96%)	4 / 201 (1.99%)	7 / 201 (3.48%)
occurrences (all)	6	4	7
Viral rash			
subjects affected / exposed	1 / 203 (0.49%)	1 / 201 (0.50%)	1 / 201 (0.50%)
occurrences (all)	1	1	1
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 203 (1.48%)	1 / 201 (0.50%)	1 / 201 (0.50%)
occurrences (all)	3	1	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 203 (1.48%)	1 / 201 (0.50%)	1 / 201 (0.50%)
occurrences (all)	3	1	1
Polydipsia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	ACWY2d Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	196 / 197 (99.49%)		
General disorders and administration site conditions			
Crying			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Gait disturbance			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Influenza like illness			

subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Injection site bruising			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Injection site mass			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	19 / 197 (9.64%)		
occurrences (all)	19		
Swelling face			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Vaccination site bruising			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Vaccination site pain			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Redness	Additional description: Number of subjects evaluable for this local reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[1]	88 / 196 (44.90%)		
occurrences (all)	88		
Pain	Additional description: Number of subjects evaluable for this local reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	91 / 196 (46.43%)		
occurrences (all)	91		
Swelling	Additional description: Number of subjects evaluable for this local reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[3]	57 / 196 (29.08%)		
occurrences (all)	57		

Irritability/Fussiness	Additional description: Number of subjects evaluable for this general reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[4]	116 / 196 (59.18%)		
occurrences (all)	116		
Drowsiness	Additional description: Number of subjects evaluable for this general reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[5]	99 / 196 (50.51%)		
occurrences (all)	99		
Loss Of Appetite	Additional description: Number of subjects evaluable for this general reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[6]	78 / 196 (39.80%)		
occurrences (all)	78		
Temperature/(Rectal) (°C)	Additional description: Number of subjects evaluable for this general reaction.		
alternative assessment type: Systematic			
subjects affected / exposed[7]	46 / 196 (23.47%)		
occurrences (all)	46		
Immune system disorders			
Food allergy			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Hypersensitivity			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Immunisation reaction			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Balanoposthitis			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Genital rash			

subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Vulvovaginal adhesion			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Vulvovaginal pruritus			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	2 / 197 (1.02%)		
occurrences (all)	2		
Catarrh			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	21 / 197 (10.66%)		
occurrences (all)	21		
Epistaxis			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	4 / 197 (2.03%)		
occurrences (all)	4		
Nasal disorder			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Nasal mucosal discolouration			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Respiratory symptom			

subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Respiratory disorder			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	7 / 197 (3.55%)		
occurrences (all)	7		
Wheezing			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Autism spectrum disorder			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Initial insomnia			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Fear			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	6 / 197 (3.05%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	3 / 197 (1.52%)		
occurrences (all)	3		
Investigations			
Body temperature			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Body temperature increased			

subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	2 / 197 (1.02%)		
occurrences (all)	2		
Head injury			
subjects affected / exposed	2 / 197 (1.02%)		
occurrences (all)	2		
Limb injury			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Skin laceration			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Soft tissue injury			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Thermal burn			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Tibia fracture			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Wound			

subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Febrile convulsion			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Poor quality sleep			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Seizure			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Eye disorders			
Corneal erosion			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Eye inflammation			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Ocular hyperaemia			

subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Abdominal pain upper			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Abnormal faeces			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Aphthous ulcer			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Coeliac disease			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	14 / 197 (7.11%)		
occurrences (all)	14		
Dyspepsia			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Enteritis			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Faeces soft			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		

Mouth ulceration			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Teething			
subjects affected / exposed	14 / 197 (7.11%)		
occurrences (all)	14		
Tooth disorder			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	17 / 197 (8.63%)		
occurrences (all)	17		
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Dermatitis contact			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	4 / 197 (2.03%)		
occurrences (all)	4		
Dermatitis diaper			
subjects affected / exposed	5 / 197 (2.54%)		
occurrences (all)	5		
Intertrigo			

subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Miliaria			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	9 / 197 (4.57%)		
occurrences (all)	9		
Petechiae			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Rash erythematous			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Rash macular			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	1 / 197 (0.51%)		
occurrences (all)	1		
Rash morbilliform			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Skin lesion			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 197 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	3 / 197 (1.52%)		
occurrences (all)	3		
Bronchitis			
subjects affected / exposed	3 / 197 (1.52%)		
occurrences (all)	3		

Conjunctivitis				
subjects affected / exposed	9 / 197 (4.57%)			
occurrences (all)	9			
Coxsackie viral infection				
subjects affected / exposed	2 / 197 (1.02%)			
occurrences (all)	2			
Croup infectious				
subjects affected / exposed	3 / 197 (1.52%)			
occurrences (all)	3			
Cystitis				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Dermatitis infected				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Ear infection				
subjects affected / exposed	6 / 197 (3.05%)			
occurrences (all)	6			
Erythema infectiosum				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Exanthema subitum				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Eye infection				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Eyelid infection				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Fungal infection				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Fungal skin infection				
subjects affected / exposed	2 / 197 (1.02%)			
occurrences (all)	2			

Gastroenteritis				
subjects affected / exposed	4 / 197 (2.03%)			
occurrences (all)	4			
Gastrointestinal bacterial infection				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Hand-foot-and-mouth disease				
subjects affected / exposed	4 / 197 (2.03%)			
occurrences (all)	4			
Herpangina				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Hordeolum				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	2 / 197 (1.02%)			
occurrences (all)	2			
Infected bite				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Laryngitis				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Lower respiratory tract infection				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Measles				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	17 / 197 (8.63%)			
occurrences (all)	17			

Oral candidiasis				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	8 / 197 (4.06%)			
occurrences (all)	8			
Otitis media acute				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Otosalpingitis				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Periodontitis				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Periorbital cellulitis				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	3 / 197 (1.52%)			
occurrences (all)	3			
Pharyngotonsillitis				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Pulmonary tuberculosis				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Rhinitis				
subjects affected / exposed	5 / 197 (2.54%)			
occurrences (all)	5			

Roseola				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Skin bacterial infection				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Staphylococcal infection				
subjects affected / exposed	1 / 197 (0.51%)			
occurrences (all)	1			
Tinea infection				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Tinea versicolour				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	5 / 197 (2.54%)			
occurrences (all)	5			
Upper respiratory tract infection				
subjects affected / exposed	28 / 197 (14.21%)			
occurrences (all)	28			
Urinary tract infection				
subjects affected / exposed	0 / 197 (0.00%)			
occurrences (all)	0			
Varicella				
subjects affected / exposed	4 / 197 (2.03%)			
occurrences (all)	4			
Viral infection				
subjects affected / exposed	12 / 197 (6.09%)			
occurrences (all)	12			
Viral rash				
subjects affected / exposed	2 / 197 (1.02%)			
occurrences (all)	2			

Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	4 / 197 (2.03%) 4		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) Polydipsia subjects affected / exposed occurrences (all)	 4 / 197 (2.03%) 4 1 / 197 (0.51%) 1		

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: Number of subjects exposed here are for this particular local/systemic event and is different from total number of subjects exposed for any adverse event.
[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: Number of subjects exposed here are for this particular local/systemic event and is different from total number of subjects exposed for any adverse event.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of subjects exposed here are for this particular local/systemic event and is different from total number of subjects exposed for any adverse event.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of subjects exposed here are for this particular local/systemic event and is different from total number of subjects exposed for any adverse event.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of subjects exposed here are for this particular local/systemic event and is different from total number of subjects exposed for any adverse event.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of subjects exposed here are for this particular local/systemic event and is different from total number of subjects exposed for any adverse event.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of subjects exposed here are for this particular local/systemic event and is different from total number of subjects exposed for any adverse event.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 January 2016	Sections updated/added in line with standard Pfizer policy: Section 8.1.2 Definition of an adverse event. Section 8.2 Detecting and recording adverse events, serious adverse events, new onset of chronic illnesses (NOCIs), and Guillain-Barre syndrome (GBS). Section 11.7 Reporting of safety issues and serious breaches of the protocol or ICH GCP.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported