Clinical trial results:
A phase III, open, multi-centre, controlled study to evaluate the long-term antibody persistence at 2, 3, 4, 5 and 6 years after a booster dose of meningococcal serogroup A, C, W-135, Y- tetanus toxoid conjugate vaccine (MenACWY-TT) or Meningitec ® administered in healthy 5-year-old children in study MENACWY-TT-048 EXT: 039 Y2, 3, 4, 5 (112036), who were primed with the same vaccine in study MENACWY-TT-039 (109670) at 12 through 23 months of age.

Summary

EudraCT number	2012-005816-25
Trial protocol	FI
Global end of trial date	08 November 2017

Results information

Result version number	v1
This version publication date	12 May 2018
First version publication date	12 May 2018

Trial information

Trial identification

Sponsor protocol code	C0921001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01900899
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 110017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 18007181021, 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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 January 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the persistence and safety of meningococcal antibodies in terms of the percentage of subjects with rSBA antibody titres >=1:8, 1:128; hSBA antibody titers >=1:4, 1:8 and geometric mean titers for each of the four serogroups at 2, 3, 4, 5, 6 years after booster vaccination of children with MenACWY-TT or Meningitec.

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	16 July 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Safety
Long term follow-up duration	6 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 184
Worldwide total number of subjects	184
EEA total number of subjects	184

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	184
Adolescents (12-17 years)	0
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

In this study, subjects from the study MENACWY-TT-039 (NCT01900899) and MENACWY-TT-048 EXT (NCT01900899) were followed up for persistence of immune response and safety for a maximum duration of 6 years.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	MenACWY-TT vaccine

Arm description:

Subjects who received single 0.5 milliliter (mL) dose of meningococcal A, C, W-135, Y-tetanus toxoid conjugate (MenACWY-TT) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.

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 who received single 0.5 mL dose of meningococcal A, C, W-135, Y-tetanus toxoid conjugate (MenACWY-TT) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.

Arm title	MenCCRM vaccine

Arm description:

Subjects who received single 0.5 mL dose of meningococcal serogroup C CRM197 conjugated (MenCCRM) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.

Arm type	Active comparator
Investigational medicinal product name	MenCCRM vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects who received single 0.5 mL dose of meningococcal serogroup CCRM197 conjugated (MenCCRM) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.

Number of subjects in period 1	MenACWY-TT vaccine	MenCCRM vaccine
Started	159	25
Completed	150	24
Not completed	9	1
Consent withdrawn by subject	7	1
Migrated from study area	2	-

Baseline characteristics

Reporting groups	
Reporting group title	MenACWY-TT vaccine
Reporting group description:	
Subjects who received single 0.5 milliliter (mL) dose of meningococcal A, C, W-135, Y-tetanus toxoid conjugate (MenACWY-TT) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.	
Reporting group title	MenCCRM vaccine
Reporting group description:	
Subjects who received single 0.5 mL dose of meningococcal serogroup C CRM197 conjugated (MenCCRM) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.	

Reporting group values	MenACWY-TT vaccine	MenCCRM vaccine	Total
Number of subjects	159	25	184
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)	0	0	0
Children (2-11 years)	159	25	184
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	90.2	89.6	
standard deviation	± 6.06	± 5.56	-
Sex: Female, Male Units: Subjects			
Female	74	10	84
Male	85	15	100
Race/Ethnicity, Customized Units: Subjects			
Race: White-Caucasian	158	24	182
Race: Other	1	1	2
Race/Ethnicity, Customized Units: Subjects			
Ethnicity: American hispanic	0	1	1
Ethnicity: Non American hispanic	159	24	183

End points

End points reporting groups

Reporting group title	MenACWY-TT vaccine

Reporting group description:

Subjects who received single 0.5 milliliter (mL) dose of meningococcal A, C, W-135, Y-tetanus toxoid conjugate (MenACWY-TT) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.

Reporting group title	MenCCRM vaccine

Reporting group description:

Subjects who received single 0.5 mL dose of meningococcal serogroup C CRM197 conjugated (MenCCRM) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.

Primary: Percentage of Subjects With rSBA-Antibody Titers >=1:8 For Each of the 4 Serogroups at 24 months After Booster Vaccination

End point title	Percentage of Subjects With rSBA-Antibody Titers >=1:8 For Each of the 4 Serogroups at 24 months After Booster Vaccination[1]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary and booster vaccination with MenACWY-TT or Meningitec vaccine in studies MENACWY-TT-039 and MENACWY-TT-048 EXT and had available assay results for at least 1 tested antigen. N (overall number of subjects analyzed)=number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

24 months after booster Vaccination

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	123	21		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA	98.4 (94.2 to 99.8)	23.8 (8.2 to 47.2)		
rSBA-MenC	97.6 (93.0 to 99.5)	100.0 (83.9 to 100.0)		
rSBA-MenW-135	96.7 (91.9 to 99.1)	9.5 (1.2 to 30.4)		
rSBA-MenY	100.0 (97.0 to 100.0)	33.3 (14.6 to 57.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With rSBA-Antibody Titers >= 1:8 For Each of the 4 Serogroups at 36 months After Booster Vaccination

End point title	Percentage of Subjects With rSBA-Antibody Titers >= 1:8 For Each of the 4 Serogroups at 36 months After Booster Vaccination[2]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary and booster vaccination with MenACWY-TT or Meningitec vaccine in studies MENACWY-TT-039 and MENACWY-TT-048 EXT and had available assay results for at least 1 tested antigen. Here, N signifies number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

36 months after booster Vaccination

Notes:

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

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	135	22		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA	95.6 (90.6 to 98.4)	18.2 (5.2 to 40.3)		
rSBA-MenC	88.1 (81.5 to 93.1)	77.3 (54.6 to 92.2)		
rSBA-MenW-135	97.8 (93.6 to 99.5)	9.1 (1.1 to 29.2)		
rSBA-MenY	94.8 (89.6 to 97.9)	36.4 (17.2 to 59.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With rSBA-Antibody Titers >=1:8 For Each of the 4 Serogroups at 48 Months After Booster Vaccination

End point title	Percentage of Subjects With rSBA-Antibody Titers >=1:8 For Each of the 4 Serogroups at 48 Months After Booster Vaccination[3]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary and booster vaccination with MenACWY-TT or Meningitec vaccine in studies MENACWY-TT-039 and MENACWY-TT-048 EXT and had available assay results for at least 1 tested antigen. Here, N signifies number of subjects evaluable for this endpoint and n=number of subjects evaluable at specified time points only.

End point type	Primary

End point timeframe:

48 months after booster Vaccination

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	23		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA (n =139, 23)	95.0 (89.9 to 98.0)	26.1 (10.2 to 48.4)		
rSBA-MenC (n =139, 23)	88.5 (82.0 to 93.3)	100.0 (85.2 to 100.0)		
rSBA-MenW-135 (n =138, 23)	87.0 (80.2 to 92.1)	17.4 (5.0 to 38.8)		
rSBA-MenY (n =139, 23)	95.0 (89.9 to 98.0)	43.5 (23.2 to 65.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With rSBA-Antibody Titers >=1:8 For Each of the 4 Serogroups at 60 Months After Booster Vaccination

End point title	Percentage of Subjects With rSBA-Antibody Titers >=1:8 For Each of the 4 Serogroups at 60 Months After Booster Vaccination[4]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary and booster vaccination with MenACWY-TT or Meningitec vaccine in studies MENACWY-TT-039 and MENACWY-TT-048 EXT and had available assay results for at least 1 tested antigen. Here, N signifies number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

60 months after booster Vaccination

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	137	23		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA	89.8 (83.4 to 94.3)	0.0 (0.0 to 14.8)		
rSBA-MenC	80.3 (72.6 to 86.6)	78.3 (56.3 to 92.5)		
rSBA-MenW-135	88.3 (81.7 to 93.2)	13.0 (2.8 to 33.6)		

rSBA-MenY	92.7 (87.0 to 96.4)	26.1 (10.2 to 48.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With rSBA-Antibody Titers >=1:8 For Each of the 4 Serogroups at 72 Months After Booster Vaccination

End point title	Percentage of Subjects With rSBA-Antibody Titers >=1:8 For Each of the 4 Serogroups at 72 Months After Booster Vaccination[5]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary and booster vaccination with MenACWY-TT or Meningitec vaccine in studies MENACWY-TT-039 and MENACWY-TT-048 EXT and had available assay results for at least 1 tested antigen. Here, N signifies number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

72 Months after booster Vaccination

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134	23		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA	92.5 (86.7 to 96.4)	8.7 (1.1 to 28.0)		
rSBA-MenC	71.6 (63.2 to 79.1)	65.2 (42.7 to 83.6)		
rSBA-MenW-135	85.8 (78.7 to 91.2)	13.0 (2.8 to 33.6)		
rSBA-MenY	94.0 (88.6 to 97.4)	13.0 (2.8 to 33.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Serum Bactericidal Assay Using hSBA-Antibody Titers >=1:4, >=1:8 and rSBA-Antibody Titers >=1:128 for Each of the 4 Serogroups

End point title	Percentage of Subjects With Serum Bactericidal Assay Using hSBA-Antibody Titers >=1:4, >=1:8 and rSBA-Antibody Titers >=1:128 for Each of the 4 Serogroups

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary and booster vaccination with MenACWY-TT or Meningitec vaccine in studies MENACWY-TT-039 and MENACWY-TT-048 EXT and had available assay results for at least 1 tested antigen. Here, N signifies number of subjects evaluable for this endpoint and n=number of subjects evaluable at specified time points only.

End point type	Secondary

End point timeframe:

24, 36, 48, 60 and 72 months after booster Vaccination

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	23		
Units: percentage of subjects				
number (confidence interval 95%)				
Month 24: rSBA-MenA-1:128 (n =123,21)	95.1 (89.7 to 98.2)	14.3 (3.0 to 36.3)		
Month 24: rSBA-MenC-1:128 (n =123,21)	74.8 (66.2 to 82.2)	85.7 (63.7 to 97.0)		
Month 24: rSBA-MenW-135-1:128 (n =123,21)	94.3 (88.6 to 97.7)	9.5 (1.2 to 30.4)		
Month 24: rSBA-MenY-1:128 (n =123,21)	94.3 (88.6 to 97.7)	33.3 (14.6 to 57.0)		
Month 36: rSBA-MenA-1:128 (n =135,22)	83.0 (75.5 to 88.9)	13.6 (2.9 to 34.9)		
Month 36: rSBA-MenC-1:128 (n =135,22)	46.7 (38.0 to 55.4)	40.9 (20.7 to 63.6)		
Month 36: rSBA-MenW-135-1:128 (n =135,22)	88.1 (81.5 to 93.1)	9.1 (1.1 to 29.2)		
Month 36: rSBA-MenY-1:128 (n =135,22)	84.4 (77.2 to 90.1)	36.4 (17.2 to 59.3)		
Month 48: rSBA-MenA-1:128 (n =139,23)	83.5 (76.2 to 89.2)	17.4 (5.0 to 38.8)		
Month 48: rSBA-MenC-1:128 (n =139,23)	46.0 (37.6 to 54.7)	47.8 (26.8 to 69.4)		
Month 48: rSBA-MenW-135-1:128 (n =138,23)	73.9 (65.8 to 81.0)	17.4 (5.0 to 38.8)		
Month 48: rSBA-MenY-1:128 (n =139,23)	82.0 (74.6 to 88.0)	43.5 (23.2 to 65.5)		
Month 60: rSBA-MenA-1:128 (n =137,23)	73.0 (64.7 to 80.2)	0.0 (0.0 to 14.8)		
Month 60: rSBA-MenC-1:128 (n =137,23)	47.4 (38.9 to 56.1)	43.5 (23.2 to 65.5)		
Month 60: rSBA-MenW-135-1:128 (n =137,23)	69.3 (60.9 to 76.9)	13.0 (2.8 to 33.6)		
Month 60: rSBA-MenY-1:128 (n =137,23)	77.4 (69.4 to 84.1)	21.7 (7.5 to 43.7)		
Month 72: rSBA-MenA-1:128 (n =134,23)	78.4 (70.4 to 85.0)	8.7 (1.1 to 28.0)		
Month 72: rSBA-MenC-1:128 (n =134,23)	40.3 (31.9 to 49.1)	34.8 (16.4 to 57.3)		
Month 72: rSBA-MenW-135-1:128 (n =134,23)	67.2 (58.5 to 75.0)	13.0 (2.8 to 33.6)		
Month 72: rSBA-MenY-1:128 (n =134,23)	75.4 (67.2 to 82.4)	13.0 (2.8 to 33.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Bactericidal Assay Using hSBA and rSBA Geometric Mean Titers (GMTs) for Each of the 4 Serogroups

End point title	Serum Bactericidal Assay Using hSBA and rSBA Geometric Mean Titers (GMTs) for Each of the 4 Serogroups

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary and booster vaccination with MenACWY-TT or Meningitec vaccine in studies MENACWY-TT-039 and MENACWY-TT-048 EXT and had available assay results for at least 1 tested antigen. Here, N signifies number of subjects evaluable for this endpoint and n=number of subjects evaluable at specified time points only. 99999 represents CI was not estimable due to the lack of variability of geometric means.

End point type	Secondary

End point timeframe:

24, 36, 48, 60 and 72 months after booster Vaccination

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	23		
Units: titers				
geometric mean (confidence interval 95%)				
Month 24: rSBA-MenA (n =123,21)	1071.2 (821.9 to 1396.2)	9.1 (3.9 to 21.6)		
Month 24: rSBA-MenC (n =123,21)	174.5 (137.5 to 221.5)	224.3 (134.1 to 375.4)		
Month 24: rSBA-MenW-135 (n =123,21)	859.9 (641.6 to 1152.3)	6.6 (3.2 to 13.4)		
Month 24: rSBA-MenY (n =123,21)	734.4 (584.6 to 922.5)	18.9 (6.6 to 53.7)		
Month 36: rSBA-MenA (n =135,22)	376.3 (280.7 to 504.3)	8.8 (3.9 to 19.6)		
Month 36: rSBA-MenC (n =135,22)	70.6 (53.3 to 93.3)	54.7 (25.0 to 119.5)		
Month 36: rSBA-MenW-135 (n =135,22)	544.5 (418.0 to 709.4)	6.4 (3.3 to 12.7)		
Month 36: rSBA-MenY (n =135,22)	416.9 (313.3 to 554.9)	20.6 (7.6 to 56.1)		
Month 48: rSBA-MenA (n =139,23)	413.2 (310.3 to 550.2)	10.8 (4.7 to 24.7)		
Month 48: rSBA-MenC (n =139,23)	69.0 (52.5 to 90.7)	62.1 (32.1 to 120.3)		
Month 48: rSBA-MenW-135 (n =138,23)	224.7 (158.6 to 318.2)	9.3 (4.1 to 21.1)		

Month 48: rSBA-MenY (n =139,23)	335.1 (254.7 to 440.9)	28.4 (10.3 to 77.8)		
Month 60: rSBA-MenA (n =137,23)	229.0 (163.0 to 321.9)	4.0 (-99999 to 99999)		
Month 60: rSBA-MenC (n =137,23)	66.0 (48.1 to 90.5)	47.3 (19.0 to 117.9)		
Month 60: rSBA-MenW-135 (n =137,23)	184.3 (130.3 to 260.6)	8.0 (3.6 to 17.8)		
Month 60: rSBA-MenY (n =137,23)	265.2 (190.9 to 368.4)	13.0 (5.2 to 32.3)		
Month 72: rSBA-MenA (n =134,23)	297.4 (214.4 to 412.5)	5.7 (3.4 to 9.6)		
Month 72: rSBA-MenC (n =134,23)	39.6 (28.6 to 54.6)	33.0 (14.7 to 74.2)		
Month 72: rSBA-MenW-135 (n =134,23)	171.9 (117.5 to 251.4)	7.3 (3.7 to 14.6)		
Month 72: rSBA-MenY (n =134,23)	260.6 (188.6 to 358.5)	8.8 (3.5 to 21.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Serious Adverse Events

End point title	Number of Subjects With Treatment Emergent Serious Adverse Events

End point description:

An Adverse event (AE) was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Serious AE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent are events between first dose of study drug and up to 72 months after last dose of study drug that were absent before treatment or that worsened relative to pretreatment state. All eligible subjects who received primary and booster vaccination with MenACWY-TT or Meningitec vaccine in studies MENACWY-TT-039 and MENACWY-TT-048 EXT and had available assay results for at least 1 tested antigen.

End point type	Secondary

End point timeframe:

Baseline up to the Month 72 after booster vaccination (up to 6 years)

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	25		
Units: subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Serum Bactericidal Assay Using hSBA-Antibody Titers >=1:4 and >=1:8 for Each of the 4 Serogroups

End point title	Percentage of Subjects With Serum Bactericidal Assay Using hSBA-Antibody Titers >=1:4 and >=1:8 for Each of the 4 Serogroups

End point description:

Data regarding the results of the hSBA assays for each of the 4 meningococcal vaccine groups was not summarized within 6 months of primary completion date (PCD). This will be posted once the assay results are available and prior to within 12 months of primary completion date.

End point type	Secondary

End point timeframe:

24, 36, 48, 60 and 72 months after booster Vaccination

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[6]	0[7]		
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)		

Notes:

[6] - Data for hSBA assays for each of the four vaccine groups will be reported within 12 months of PCD

[7] - Data for hSBA assays for each of the four vaccine groups will be reported within 12 months of PCD

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Bactericidal Assay Using hSBA Geometric Mean Titers (GMTs) for Each of the 4 Serogroups

End point title	Serum Bactericidal Assay Using hSBA Geometric Mean Titers (GMTs) for Each of the 4 Serogroups

End point description:

Data regarding the results of the hSBA assays for each of the 4 meningococcal vaccine groups was not summarized within 6 months of primary completion date. This will be posted once the assay results are available and prior to within 12 months of primary completion date.

End point type	Secondary

End point timeframe:

24, 36, 48, 60 and 72 months after booster Vaccination

End point values	MenACWY-TT vaccine	MenCCRM vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[8]	0[9]		
Units: titers				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[8] - Data for hSBA assays for each of the four vaccine groups will be reported within 12 months of PCD

[9] - Data for hSBA assays for each of the four vaccine groups will be reported within 12 months of PCD

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to the Month 72 after booster vaccination (up to 6 years)

Adverse event reporting additional description:

Same event may appear as both an AE and Serious AE. However, what is presented are distinct events. An event may be categorized 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	20.0

Reporting groups

Reporting group title	MenCCRM vaccine

Reporting group description:

Subjects who received single 0.5 mL dose of meningococcal serogroup C CRM197 conjugated (MenCCRM) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.

Reporting group title	MenACWY-TT vaccine

Reporting group description:

Subjects who received single 0.5 mL dose of meningococcal A, C, W-135, Y-tetanus toxoid conjugate (MenACWY-TT) vaccine as primary vaccination in study MENACWY-TT-039 and as booster dose in study MENACWY-TT-048 EXT, intramuscularly with a follow up period of 4 years, were observed in this study for a maximum duration of 6 years.

Serious adverse events	MenCCRM vaccine	MenACWY-TT vaccine	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 159 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	MenCCRM vaccine	MenACWY-TT vaccine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	1 / 159 (0.63%)	
Musculoskeletal and connective tissue disorders			
Juvenile idiopathic arthritis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 January 2016	Protocol was amended to reflect sponsorship change to Pfizer following the acquisition of the GSK meningococcal vaccine Nimenrix by Pfizer on 01 October 2015.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported