Clinical trial results:
The Long-Term Antibody Persistence Of Menacwy-TT Vaccine (PF-06866681) Versus Meningitec ® Or Mencevax ® ACWY In Healthy Adolescents And Adults And A Booster Dose Of Menacwy-TT Administered 10 Years Post-Primary Vaccination

Summary

EudraCT number	2013-001549-15
Trial protocol	FI
Global end of trial date	11 June 2018

Results information

Result version number	v1 (current)
This version publication date	10 March 2019
First version publication date	10 March 2019

Trial information

Trial identification

Sponsor protocol code	MenACWY-TT-100

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01962207
WHO universal trial number (UTN)	-
Other trial identifiers	Alias Study Number: C0921004

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer, Inc., Pfizer ClinicalTrials.gov Call Center, 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	11 June 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate long-term persistence of serum bactericidal (antibody) titers induced by meningococcal serogroups A, C, W 135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine as compared to meningitec when administered to individuals 1 to less than (<)2 years of age in terms of percentage of subjects with Neisseria meningitidis serogroup A (MenA), serogroup C (MenC), serogroup W-135 (MenW-135), serogroup Y (MenY) titers greater than or equal to (>=)1:8, >=1:128, geometric mean titers (GMTs) as measured by a serum bactericidal assay using rabbit complement (rSBA) in those subjects that received MenACWY-TT, MenC rSBA titers >=1:8, >=1:128, GMTs in those subjects that received meningitec. To evaluate long-term persistence of serum bactericidal (antibody) titers induced by MenACWY-TT vaccine as compared to mencevax ACWY when administered to individuals 2-10 years of age in terms of percentage of subjects with MenA, MenC, MenW-135, and MenY titres >=1:8, >=1:128 and GMTs as measured by rSBA.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 October 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 243
Worldwide total number of subjects	243
EEA total number of subjects	243

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	157
Adolescents (12-17 years)	85

Adults (18-64 years)	1
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-027 [NCT00427908] were followed up for assessment of persistence of immune response and safety for 5 years followed by receiving booster vaccination (only eligible subjects who consented) and followed up for another 6 months.

Period 1

Period 1 title	Persistence Phase (5 Years)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	MenACWY-TT Vaccine (Less Than [<] 2 Years)

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 milliliter (mL) dose of meningococcal serogroups A, C, W 135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100), they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with <2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027.

Arm title	MenCCRM (Meningitec) Vaccine(<2 Years)

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenCCRM Vaccine
Investigational medicinal product code	
Other name	Meningitec
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027.

Arm title	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with >=2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with >=2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027.

Arm title	MenPS (Mencevax ACWY) Vaccine (< 2 Years)

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenPS Vaccine
Investigational medicinal product code	
Other name	Mencevax
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027.

Number of subjects in period 1	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)
Started	76	23	115
Completed	47	10	71
Not completed	29	13	44
Eligibility criteria not fulfilled	-	-	3
Migrated/moved from study area	2	-	4
Adverse event, non-fatal	-	-	1
Missed at least 1 persistence visit	21	7	13
Consent withdrawn by subject	4	5	18
Lost to follow-up	2	1	5

Number of subjects in period 1	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Started	29
Completed	17
Not completed	12
Eligibility criteria not fulfilled	1
Migrated/moved from study area	-
Adverse event, non-fatal	-
Missed at least 1 persistence visit	5
Consent withdrawn by subject	4
Lost to follow-up	2

Period 2

Period 2 title	Booster Phase (6 Months)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	MenACWY-TT Vaccine: Less Than (<) 2 Years

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100), they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with <2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Eligible subjects from persistence phase who provided consent were enrolled in booster phase and received a single 0.5 mL booster dose of MenACWY-TT in this study.

Arm title	MenCCRM (Meningitec) Vaccine: Less Than 2 Years

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Eligible subjects from persistence phase who provided consent were enrolled in booster phase and received a single 0.5 mL booster dose of MenACWY-TT intramuscularly in this study.

Arm title	MenACWY-TT Vaccine: Greater Than or Equal to (>=) 2 Years

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with >=2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with >=2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Eligible subjects from persistence phase who provided consent were enrolled in booster phase and received a single 0.5 mL booster dose of MenACWY-TT in this study.

Arm title	MenPS (Mencevax ACWY) Vaccine: Less Than 2 Years

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Eligible subjects from persistence phase who provided consent were enrolled in booster phase and received a single 0.5 mL booster dose of MenACWY-TT in this study.

Number of subjects in period 2	MenACWY-TT Vaccine: Less Than (<) 2 Years	MenCCRM (Meningitec) Vaccine: Less Than 2 Years	MenACWY-TT Vaccine: Greater Than or Equal to (>=) 2 Years
Started	67	16	77
Completed	67	16	77

Number of subjects in period 2	MenPS (Mencevax ACWY) Vaccine: Less Than 2 Years
Started	21
Completed	21

Baseline characteristics

Reporting groups	
Reporting group title	MenACWY-TT Vaccine (Less Than [<] 2 Years)
Reporting group description:	
Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 milliliter (mL) dose of meningococcal serogroups A, C, W 135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100), they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.	
Reporting group title	MenCCRM (Meningitec) Vaccine(<2 Years)
Reporting group description:	
Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.	
Reporting group title	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)
Reporting group description:	
Persistence phase was followed up by booster phase. Persistence phase: Subjects with >=2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.	
Reporting group title	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Reporting group description:	
Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.	

Reporting group values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)
Number of subjects	76	23	115
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)	76	23	44
Adolescents (12-17 years)	0	0	70
Adults (18-64 years)	0	0	1
From 65-84 years	0	0	0

85 years and over	0	0	0

Age Continuous			
Units: years			
arithmetic mean	8.2	8.2	12.5
standard deviation	± 0.7	± 0.7	± 2.6
Sex: Female, Male			
Units: Subjects			
Female	40	12	56
Male	36	11	59
Race/Ethnicity, Customized			
Units: Subjects			
White - Arabic/North African heritage|	0	0	1
White - Caucasian/European heritage|	75	22	113
Other|	1	1	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	76	23	115
Unknown or Not Reported	0	0	0

Reporting group values	MenPS (Mencevax ACWY) Vaccine (< 2 Years)	Total	
Number of subjects	29	243	
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)	0	0	
Children (2-11 years)	14	157	
Adolescents (12-17 years)	15	85	
Adults (18-64 years)	0	1	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	12.1		
standard deviation	± 2.9	-	
Sex: Female, Male			
Units: Subjects			
Female	14	122	
Male	15	121	
Race/Ethnicity, Customized			
Units: Subjects			
White - Arabic/North African heritage|	0	1	

White - Caucasian/European heritage|	28	238	
Other|	1	4	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	29	243	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	MenACWY-TT Vaccine (Less Than [<] 2 Years)

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 milliliter (mL) dose of meningococcal serogroups A, C, W 135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100), they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Reporting group title	MenCCRM (Meningitec) Vaccine(<2 Years)

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Reporting group title	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with >=2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Reporting group title	MenPS (Mencevax ACWY) Vaccine (< 2 Years)

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Reporting group title	MenACWY-TT Vaccine: Less Than (<) 2 Years

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100), they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Reporting group title	MenCCRM (Meningitec) Vaccine: Less Than 2 Years

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Reporting group title	MenACWY-TT Vaccine: Greater Than or Equal to (>=) 2 Years

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with >=2 years of

age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Reporting group title	MenPS (Mencevax ACWY) Vaccine: Less Than 2 Years

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Primary: Persistence Phase: Percentage of Subjects With Serum Bactericidal Assay Using Rabbit Complement (rSBA) Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 6 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With Serum Bactericidal Assay Using Rabbit Complement (rSBA) Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 6 Years of Primary Vaccination[1]

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). All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec, or Mencevax ACWY during study MenACWY-TT-027 and had available assay results for at least 1 tested antigen. Here, "Overall Number of Subjects Analyzed" (N) signifies number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

6 years after primary vaccination (Year 1 of study MENACWY-TT-100)

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 analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	16	98	24
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8	51.9 (37.8 to 65.7)	18.8 (4.0 to 45.6)	79.6 (70.3 to 87.1)	12.5 (2.7 to 32.4)
rSBA-MenC: >=1:8	77.8 (64.4 to 88.0)	75.0 (47.6 to 92.7)	82.7 (73.7 to 89.6)	79.2 (57.8 to 92.9)
rSBA-MenW-135: >=1:8	33.3 (21.1 to 47.5)	12.5 (1.6 to 38.3)	73.5 (63.6 to 81.9)	12.5 (2.7 to 32.4)
rSBA-MenY: >=1:8	38.9 (25.9 to 53.1)	37.5 (15.2 to 64.6)	71.4 (61.4 to 80.1)	20.8 (7.1 to 42.2)
rSBA-MenA: >=1:28	16.7 (7.9 to 29.3)	6.3 (0.2 to 30.2)	55.1 (44.7 to 65.2)	8.3 (1.0 to 27.0)
rSBA-MenC: >=1:28	70.4 (56.4 to 82.0)	56.3 (29.9 to 80.2)	68.4 (58.2 to 77.4)	62.5 (40.6 to 81.2)

rSBA-MenW-135: >=1:28	29.6 (18.0 to 43.6)	6.3 (0.2 to 30.2)	73.5 (63.6 to 81.9)	12.5 (2.7 to 32.4)
rSBA-MenY: >=1:28	33.3 (21.1 to 47.5)	31.3 (11.0 to 58.7)	65.3 (55.0 to 74.6)	20.8 (7.1 to 42.2)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Percentage of Subjects With rSBA Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 7 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With rSBA Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 7 Years of Primary Vaccination[2]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure. "Number analyzed (n)": subjects analyzed for specified serogroup titers cut off.

End point type	Primary

End point timeframe:

7 years after primary vaccination (Year 2 of study MENACWY-TT-100)

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 analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	21	104	27
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8 (n:60, 21, 104, 27)	58.3 (44.9 to 70.9)	9.5 (1.2 to 30.4)	74.0 (64.5 to 82.1)	18.5 (6.3 to 38.1)
rSBA-MenC: >=1:8 (n:60, 21, 101, 27)	78.3 (65.8 to 87.9)	71.4 (47.8 to 88.7)	84.2 (75.6 to 90.7)	81.5 (61.9 to 93.7)
rSBA-MenW-135: >=1:8 (n:60, 21, 102, 27)	26.7 (16.1 to 39.7)	9.5 (1.2 to 30.4)	73.5 (63.9 to 81.8)	11.1 (2.4 to 29.2)
rSBA-MenY: >=1:8 (n:60, 21, 102, 27)	35.0 (23.1 to 48.4)	28.6 (11.3 to 52.2)	75.5 (66.0 to 83.5)	14.8 (4.2 to 33.7)
rSBA-MenA: >=1:28 (n:60, 21, 104, 27)	21.7 (12.1 to 34.2)	9.5 (1.2 to 30.4)	44.2 (34.5 to 54.3)	11.1 (2.4 to 29.2)
rSBA-MenC: >=1:28 (n:60, 21, 101, 27)	61.7 (48.2 to 73.9)	52.4 (29.8 to 74.3)	61.4 (51.2 to 70.9)	66.7 (46.0 to 83.5)
rSBA-MenW-135: >=1:28 (n:60, 21, 102, 27)	23.3 (13.4 to 36.0)	9.5 (1.2 to 30.4)	69.6 (59.7 to 78.3)	7.4 (0.9 to 24.3)
rSBA-MenY: >=1:28 (n:60, 21, 102, 27)	33.3 (21.7 to 46.7)	28.6 (11.3 to 52.2)	69.6 (59.7 to 78.3)	14.8 (4.2 to 33.7)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Percentage of Subjects With rSBA Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 8 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With rSBA Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 8 Years of Primary Vaccination[3]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027 and had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

8 years after primary vaccination (Year 3 of study MENACWY-TT-100)

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 analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	22	100	25
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8	47.7 (35.1 to 60.5)	4.5 (0.1 to 22.8)	70.0 (60.0 to 78.8)	24.0 (9.4 to 45.1)
rSBA-MenC: >=1:8	78.5 (66.5 to 87.7)	77.3 (54.6 to 92.2)	85.0 (76.5 to 91.4)	88.0 (68.8 to 97.5)
rSBA-MenW-135: >=1:8	29.2 (18.6 to 41.8)	13.6 (2.9 to 34.9)	76.0 (66.4 to 84.0)	20.0 (6.8 to 40.7)
rSBA-MenY: >=1:8	40.0 (28.0 to 52.9)	40.9 (20.7 to 63.6)	79.0 (69.7 to 86.5)	24.0 (9.4 to 45.1)
rSBA-MenA: >=1:28	23.1 (13.5 to 35.2)	4.5 (0.1 to 22.8)	45.0 (35.0 to 55.3)	12.0 (2.5 to 31.2)
rSBA-MenC: >=1:28	64.6 (51.8 to 76.1)	50.0 (28.2 to 71.8)	61.0 (50.7 to 70.6)	64.0 (42.5 to 82.0)
rSBA-MenW-135: >=1:28	27.7 (17.3 to 40.2)	9.1 (1.1 to 29.2)	76.0 (66.4 to 84.0)	20.0 (6.8 to 40.7)
rSBA-MenY: >=1:28	38.5 (26.7 to 51.4)	40.9 (20.7 to 63.6)	73.0 (63.2 to 81.4)	20.0 (6.8 to 40.7)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Percentage of Subjects With rSBA Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 9 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With rSBA Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 9 Years of Primary Vaccination[4]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup titers cut off.

End point type	Primary

End point timeframe:

9 years after primary vaccination (Year 4 of study MENACWY-TT-100)

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 analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	21	93	25
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA >=1:8 (n:64, 21, 93, 25)	67.2 (54.3 to 78.4)	4.8 (0.1 to 23.8)	79.6 (69.9 to 87.2)	24.0 (9.4 to 45.1)
rSBA-MenC >=1:8 (n:64, 21, 93, 25)	81.3 (69.5 to 89.9)	85.7 (63.7 to 97.0)	86.0 (77.3 to 92.3)	84.0 (63.9 to 95.5)
rSBA-MenW-135 >=1:8 (n:64, 21, 92, 25)	32.8 (21.6 to 45.7)	9.5 (1.2 to 30.4)	76.1 (66.1 to 84.4)	16.0 (4.5 to 36.1)
rSBA-MenY >=1:8 (n:64, 21, 93, 25)	42.2 (29.9 to 55.2)	47.6 (25.7 to 70.2)	66.7 (56.1 to 76.1)	20.0 (6.8 to 40.7)
rSBA-MenA >=1:28 (n:64, 21, 93, 25)	31.3 (20.2 to 44.1)	4.8 (0.1 to 23.8)	57.0 (46.3 to 67.2)	16.0 (4.5 to 36.1)
rSBA-MenC >=1:28 (n:64, 21, 93, 25)	65.6 (52.7 to 77.1)	57.1 (34.0 to 78.2)	64.5 (53.9 to 74.2)	68.0 (46.5 to 85.1)
rSBA-MenW-135 >=1:28 (n:64, 21, 92, 25)	26.6 (16.3 to 39.1)	9.5 (1.2 to 30.4)	71.7 (61.4 to 80.6)	16.0 (4.5 to 36.1)
rSBA-MenY >=1:28 (n:64, 21, 93, 25)	34.4 (22.9 to 47.3)	38.1 (18.1 to 61.6)	58.1 (47.4 to 68.2)	16.0 (4.5 to 36.1)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Percentage of Subjects With rSBA Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 10 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With rSBA Titers >= 1:8 and >=1:128 For Each of the 4 Serogroups After 10 Years of Primary Vaccination[5]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure. "n": subjects analyzed for this outcome measure for specified serogroup titers cut off.

End point type	Primary

End point timeframe:

10 years after primary vaccination (Year 4 of study MENACWY-TT-100)

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 analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	17	82	21
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA >=1:8 (n: 64, 17, 81, 21)	65.6 (52.7 to 77.1)	17.6 (3.8 to 43.4)	88.9 (80.0 to 94.8)	28.6 (11.3 to 52.2)
rSBA-MenC >=1:8 (n: 64, 17, 82, 21)	82.8 (71.3 to 91.1)	88.2 (63.6 to 98.5)	84.1 (74.4 to 91.3)	81.0 (58.1 to 94.6)
rSBA-MenW-135 >=1:8 (n: 64, 17, 82, 21)	31.3 (20.2 to 44.1)	0.0 (0.0 to 19.5)	67.1 (55.8 to 77.1)	23.8 (8.2 to 47.2)
rSBA-MenY >=1:8 (n: 64, 17, 82, 21)	43.8 (31.4 to 56.7)	35.3 (14.2 to 61.7)	65.9 (54.6 to 76.0)	23.8 (8.2 to 47.2)
rSBA-MenA >=1:28 (n: 64, 17, 81, 21)	26.6 (16.3 to 39.1)	5.9 (0.1 to 28.7)	49.4 (38.1 to 60.7)	14.3 (3.0 to 36.3)
rSBA-MenC >=1:28 (n: 64, 17, 82, 21)	64.1 (51.1 to 75.7)	58.8 (32.9 to 81.6)	65.9 (54.6 to 76.0)	66.7 (43.0 to 85.4)
rSBA-MenW-135 >=1:28 (n: 64, 17, 82, 21)	28.1 (17.6 to 40.8)	0.0 (0.0 to 19.5)	65.9 (54.6 to 76.0)	23.8 (8.2 to 47.2)
rSBA-MenY >=1:28 (n: 64, 17, 82, 21)	35.9 (24.3 to 48.9)	29.4 (10.3 to 56.0)	59.8 (48.3 to 70.4)	19.0 (5.4 to 41.9)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 6 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 6 Years of Primary Vaccination[6]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027 and had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

6 Years after primary vaccination (Year 1 of study MENACWY-TT-100)

Notes:

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

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	16	98	24
Units: titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	16.0 (9.8 to 26.1)	5.9 (3.1 to 11.3)	107.3 (66.0 to 174.3)	5.8 (3.5 to 9.6)
rSBA-MenC	161.3 (84.7 to 307.1)	103.1 (31.9 to 333.3)	192.9 (121.0 to 307.5)	98.7 (42.2 to 230.7)
rSBA-MenW-135	18.0 (9.8 to 32.9)	6.2 (3.1 to 12.3)	265.2 (154.9 to 454.1)	7.6 (3.7 to 15.6)
rSBA-MenY	21.5 (11.5 to 40.1)	21.7 (5.9 to 79.0)	136.4 (82.6 to 225.3)	11.6 (4.7 to 28.7)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 7 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 7 Years of Primary Vaccination[7]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup.

End point type	Primary

End point timeframe:

7 years after primary vaccination (Year 2 of study MENACWY-TT-100)

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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	21	104	27
Units: titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (n: 60, 21, 104, 27)	20.4 (12.1 to 34.4)	6.1 (3.3 to 11.4)	65.3 (40.5 to 105.4)	7.4 (4.0 to 13.8)
rSBA-MenC (n: 60, 21, 101, 27)	104.0 (58.0 to 186.3)	54.3 (18.5 to 158.9)	139.0 (87.8 to 220.0)	101.6 (42.1 to 245.0)

rSBA-MenW-135 (n: 60, 21, 102, 27)	13.0 (7.6 to 22.3)	6.8 (3.0 to 15.3)	206.0 (120.9 to 350.9)	6.3 (3.7 to 10.9)
rSBA-MenY (n: 60, 21, 102, 27)	19.9 (11.0 to 36.1)	18.3 (5.8 to 57.6)	152.7 (96.1 to 242.6)	8.2 (4.1 to 16.5)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 8 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 8 Years of Primary Vaccination[8]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

8 years after primary vaccination (Year 3 of study MENACWY-TT-100)

Notes:

[8] - 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 analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	22	100	25
Units: titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	15.8 (9.8 to 25.6)	4.8 (3.3 to 7.2)	51.3 (31.5 to 83.4)	7.8 (4.2 to 14.3)
rSBA-MenC	110.2 (65.9 to 184.3)	64.0 (26.0 to 157.4)	140.1 (91.3 to 214.9)	121.1 (52.2 to 281.1)
rSBA-MenW-135	15.3 (9.0 to 26.3)	6.4 (3.3 to 12.4)	252.5 (154.3 to 413.2)	11.8 (4.7 to 29.8)
rSBA-MenY	26.1 (14.4 to 47.5)	33.0 (9.8 to 111.0)	181.0 (115.0 to 284.9)	10.9 (4.8 to 24.6)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 9 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titers as Measured by rSBA

	for Each of the 4 Serogroups After 9 Years of Primary Vaccination[9]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup.

End point type	Primary

End point timeframe:

9 years after primary vaccination (Year 4 of study MENACWY-TT-100)

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: Only descriptive data was planned to be analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	21	93	25
Units: titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (n: 64, 21, 93, 25)	28.4 (16.5 to 48.9)	5.2 (3.0 to 9.0)	118.8 (71.1 to 198.6)	10.9 (4.5 to 26.2)
rSBA-MenC (n: 64, 21, 93, 25)	166.0 (92.3 to 298.7)	92.0 (32.7 to 259.1)	176.4 (106.8 to 291.3)	164.3 (66.5 to 405.8)
rSBA-MenW-135 (n: 64, 21, 92, 25)	17.3 (9.7 to 30.8)	6.6 (3.2 to 13.6)	274.0 (155.8 to 481.7)	9.7 (4.0 to 23.3)
rSBA-MenY (n: 64, 21, 93, 25)	23.1 (13.0 to 41.2)	32.0 (10.6 to 96.3)	106.2 (61.5 to 183.4)	10.0 (4.4 to 22.9)

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 10 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titers as Measured by rSBA for Each of the 4 Serogroups After 10 Years of Primary Vaccination[10]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup. Here, 99999 signifies data was not calculated due to CI was not estimable due to the lack of variability of of antibody titer (all subjects had titers below the cutoff value 1:8).

End point type	Primary

End point timeframe:

10 years after primary vaccination (Year 5 of study MENACWY-TT-100)

Notes:

[10] - 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 analyzed for this endpoint.

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	17	82	21
Units: titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (n: 64, 17, 81, 21)	29.3 (16.8 to 51.3)	5.8 (3.2 to 10.6)	106.0 (63.7 to 176.4)	9.1 (4.0 to 20.7)
rSBA-MenC (n: 64, 17, 82, 21)	132.2 (74.5 to 234.6)	81.7 (29.2 to 229.2)	175.0 (104.7 to 292.4)	105.0 (37.2 to 296.4)
rSBA-MenW-135 (n: 64, 17, 82, 21)	16.7 (9.5 to 29.3)	4.0 (-99999 to 99999)	187.2 (101.0 to 347.1)	14.0 (4.8 to 41.2)
rSBA-MenY (n: 64, 17, 82, 21)	25.8 (14.0 to 47.3)	22.2 (5.8 to 84.2)	90.5 (51.5 to 159.2)	12.7 (4.2 to 38.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Persistence Phase: Percentage of Subjects With Serum Bactericidal Assay Using Human Complement (hSBA) Titers >=1:4 and >=1:8 for Each of the 4 Serogroups After 6, 7, 8, 9 and 10 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With Serum Bactericidal Assay Using Human Complement (hSBA) Titers >=1:4 and >=1:8 for Each of the 4 Serogroups After 6, 7, 8, 9 and 10 Years of Primary Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup titers cut off.

End point type	Secondary

End point timeframe:

6, 7, 8, 9 and 10 years after primary vaccination (Year 1, 2, 3, 4 and 5 of study MENACWY-TT-100)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	22	100	27
Units: percentage of subjects				
number (confidence interval 95%)				

Year 1: hSBA-MenA >=1:4 (n:44, 14, 90, 21)	34.1 (20.5 to 49.9)	28.6 (8.4 to 58.1)	42.2 (31.9 to 53.1)	42.9 (21.8 to 66.0)
Year 2: hSBA-MenA >=1:4 (n:60, 21, 99, 26)	26.7 (16.1 to 39.7)	14.3 (3.0 to 36.3)	26.3 (17.9 to 36.1)	26.9 (11.6 to 47.8)
Year 3: hSBA-MenA >=1:4 (n:64, 22, 97, 25)	32.8 (21.6 to 45.7)	27.3 (10.7 to 50.2)	28.9 (20.1 to 39.0)	40.0 (21.1 to 61.3)
Year 4: hSBA-MenA >=1:4 (n:63, 20, 86, 23)	39.7 (27.6 to 52.8)	30.0 (11.9 to 54.3)	43.0 (32.4 to 54.2)	30.4 (13.2 to 52.9)
Year 5: hSBA-MenA >=1:4 (n:61, 16, 69, 21)	31.1 (19.9 to 44.3)	25.0 (7.3 to 52.4)	34.8 (23.7 to 47.2)	33.3 (14.6 to 57.0)
Year 1: hSBA-MenC >=1:4 (n:53, 16, 97, 24)	92.5 (81.8 to 97.9)	93.8 (69.8 to 99.8)	93.8 (87.0 to 97.7)	100.0 (85.8 to 100.0)
Year 2: hSBA-MenC >=1:4 (n:59, 20, 96, 26)	89.8 (79.2 to 96.2)	100.0 (83.2 to 100.0)	88.5 (80.4 to 94.1)	92.3 (74.9 to 99.1)
Year 3: hSBA-MenC >=1:4 (n:64, 22, 96, 25)	92.2 (82.7 to 97.4)	95.5 (77.2 to 99.9)	89.6 (81.7 to 94.9)	96.0 (79.6 to 99.9)
Year 4: hSBA-MenC >=1:4 (n:63, 20, 90, 24)	90.5 (80.4 to 96.4)	95.0 (75.1 to 99.9)	86.7 (77.9 to 92.9)	91.7 (73.0 to 99.0)
Year 5: hSBA-MenC >=1:4 (n:62, 16, 79, 21)	91.9 (82.2 to 97.3)	93.8 (69.8 to 99.8)	91.1 (82.6 to 96.4)	100.0 (83.9 to 100.0)
Year 1: hSBA-MenW-135>=1:4 (n:47, 15, 92, 23)	70.2 (55.1 to 82.7)	13.3 (1.7 to 40.5)	81.5 (72.1 to 88.9)	30.4 (13.2 to 52.9)
Year 2: hSBA-MenW-135>=1:4 (n:58, 20, 98, 27)	60.3 (46.6 to 73.0)	20.0 (5.7 to 43.7)	79.6 (70.3 to 87.1)	18.5 (6.3 to 38.1)
Year 3: hSBA-MenW-135>=1:4 (n:64, 21, 94, 25)	39.1 (27.1 to 52.1)	19.0 (5.4 to 41.9)	56.4 (45.8 to 66.6)	12.0 (2.5 to 31.2)
Year 4: hSBA-MenW-135>=1:4 (n:58, 16, 79, 21)	44.8 (31.7 to 58.5)	18.8 (4.0 to 45.6)	68.4 (56.9 to 78.4)	9.5 (1.2 to 30.4)
Year 5: hSBA-MenW-135>=1:4 (n:54, 14, 67, 19)	44.4 (30.9 to 58.6)	21.4 (4.7 to 50.8)	61.2 (48.5 to 72.9)	26.3 (9.1 to 51.2)
Year 1: hSBA-MenY>=1:4 (n:41, 14, 89, 24)	31.7 (18.1 to 48.1)	7.1 (0.2 to 33.9)	65.2 (54.3 to 75.0)	25.0 (9.8 to 46.7)
Year 2: hSBA-MenY>=1:4 (n:56, 21, 100, 27)	51.8 (38.0 to 65.3)	33.3 (14.6 to 57.0)	75.0 (65.3 to 83.1)	40.7 (22.4 to 61.2)
Year 3: hSBA-MenY>=1:4 (n:63, 21, 93, 23)	50.8 (37.9 to 63.6)	38.1 (18.1 to 61.6)	72.0 (61.8 to 80.9)	34.8 (16.4 to 57.3)
Year 4: hSBA-MenY>=1:4 (n:61, 19, 84, 22)	32.8 (21.3 to 46.0)	26.3 (9.1 to 51.2)	67.9 (56.8 to 77.6)	27.3 (10.7 to 50.2)
Year 5: hSBA-MenY>=1:4 (n:58, 15, 73, 18)	41.4 (28.6 to 55.1)	40.0 (16.3 to 67.7)	72.6 (60.9 to 82.4)	44.4 (21.5 to 69.2)
Year 1: hSBA-MenA>=1:8 (n:44, 14, 90, 21)	31.8 (18.6 to 47.6)	28.6 (8.4 to 58.1)	41.1 (30.8 to 52.0)	33.3 (14.6 to 57.0)
Year 2: hSBA-MenA>=1:8 (n:60, 21, 99, 26)	25.0 (14.7 to 37.9)	14.3 (3.0 to 36.3)	26.3 (17.9 to 36.1)	23.1 (9.0 to 43.6)
Year 3: hSBA-MenA>=1:8 (n:64, 22, 97, 25)	32.8 (21.6 to 45.7)	27.3 (10.7 to 50.2)	28.9 (20.1 to 39.0)	36.0 (18.0 to 57.5)
Year 4: hSBA-MenA>=1:8 (n:63, 20, 86, 23)	30.2 (19.2 to 43.0)	20.0 (5.7 to 43.7)	43.0 (32.4 to 54.2)	26.1 (10.2 to 48.4)
Year 5: hSBA-MenA>=1:8 (n:61, 16, 69, 21)	26.2 (15.8 to 39.1)	18.8 (4.0 to 45.6)	33.3 (22.4 to 45.7)	28.6 (11.3 to 52.2)
Year 1: hSBA-MenC>=1:8 (n:53, 16, 97, 24)	92.5 (81.8 to 97.9)	93.8 (69.8 to 99.8)	93.8 (87.0 to 97.7)	100.0 (85.8 to 100.0)
Year 2: hSBA-MenC>=1:8 (n:59, 20, 96, 26)	89.8 (79.2 to 96.2)	100.0 (83.2 to 100.0)	88.5 (80.4 to 94.1)	92.3 (74.9 to 99.1)
Year 3: hSBA-MenC>=1:8 (n:64, 22, 96, 25)	92.2 (82.7 to 97.4)	95.5 (77.2 to 99.9)	89.6 (81.7 to 94.9)	96.0 (79.6 to 99.9)
Year 4: hSBA-MenC>=1:8 (n:63, 20, 90, 24)	90.5 (80.4 to 96.4)	95.0 (75.1 to 99.9)	85.6 (76.6 to 92.1)	91.7 (73.0 to 99.0)
Year 5: hSBA-MenC>=1:8 (n:62, 16, 79, 21)	91.9 (82.2 to 97.3)	93.8 (69.8 to 99.8)	91.1 (82.6 to 96.4)	100.0 (83.9 to 100.0)
Year 1: hSBA-MenW-135 >=1:8 (n:47, 15, 92, 23)	70.2 (55.1 to 82.7)	13.3 (1.7 to 40.5)	81.5 (72.1 to 88.9)	30.4 (13.2 to 52.9)

Year 2: hSBA-MenW-135 >=1:8 (n:58, 20, 98, 27)	60.3 (46.6 to 73.0)	20.0 (5.7 to 43.7)	79.6 (70.3 to 87.1)	18.5 (6.3 to 38.1)
Year 3: hSBA-MenW-135 >=1:8 (n:64, 21, 94, 25)	39.1 (27.1 to 52.1)	19.0 (5.4 to 41.9)	56.4 (45.8 to 66.6)	12.0 (2.5 to 31.2)
Year 4: hSBA-MenW-135 >=1:8 (n:58, 16, 79, 21)	44.8 (31.7 to 58.5)	18.8 (4.0 to 45.6)	67.1 (55.6 to 77.3)	9.5 (1.2 to 30.4)
Year 5: hSBA-MenW-135 >=1:8 (n:54, 14, 67, 19)	44.4 (30.9 to 58.6)	21.4 (4.7 to 50.8)	61.2 (48.5 to 72.9)	26.3 (9.1 to 51.2)
Year 1: hSBA-MenY >=1:8 (n:41, 14, 89, 24)	31.7 (18.1 to 48.1)	7.1 (0.2 to 33.9)	65.2 (54.3 to 75.0)	25.0 (9.8 to 46.7)
Year 2: hSBA-MenY >=1:8 (n:56, 21, 100, 27)	51.8 (38.0 to 65.3)	33.3 (14.6 to 57.0)	75.0 (65.3 to 83.1)	40.7 (22.4 to 61.2)
Year 3: hSBA-MenY >=1:8 (n:63, 21, 93, 23)	50.8 (37.9 to 63.6)	38.1 (18.1 to 61.6)	72.0 (61.8 to 80.9)	34.8 (16.4 to 57.3)
Year 4: hSBA-MenY >=1:8 (n:61, 19, 84, 22)	32.8 (21.3 to 46.0)	26.3 (9.1 to 51.2)	67.9 (56.8 to 77.6)	27.3 (10.7 to 50.2)
Year 5: hSBA-MenY >=1:8 (n:58, 15, 73, 18)	41.4 (28.6 to 55.1)	40.0 (16.3 to 67.7)	72.6 (60.9 to 82.4)	44.4 (21.5 to 69.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Persistence Phase: Geometric Mean Titers as Measured by hSBA for Each of the 4 Serogroups After 6, 7, 8, 9 and 10 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titers as Measured by hSBA for Each of the 4 Serogroups After 6, 7, 8, 9 and 10 Years of Primary Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT, Meningitec or Mencevax ACWY in Study MenACWY-TT-027, had available assay results for at least 1 tested antigen. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup.

End point type	Secondary

End point timeframe:

6, 7, 8, 9 and 10 years after primary vaccination (Year 1, 2, 3, 4 and 5 of study MENACWY-TT-100)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	22	100	27
Units: titers				
geometric mean (confidence interval 95%)				
Year 1: hSBA-MenA(n:44, 14, 90, 21)	4.7 (3.2 to 7.1)	3.5 (2.1 to 5.8)	6.5 (4.8 to 8.8)	5.9 (3.0 to 11.7)
Year 2: hSBA-MenA(n:60, 21, 99, 26)	3.8 (2.9 to 5.2)	2.8 (1.8 to 4.2)	4.5 (3.4 to 6.0)	4.7 (2.4 to 9.0)
Year 3: hSBA-MenA(n:64, 22, 97, 25)	5.0 (3.5 to 7.1)	3.7 (2.2 to 6.1)	4.6 (3.4 to 6.0)	6.7 (3.2 to 14.0)
Year 4: hSBA-MenA(n:63, 20, 86, 23)	4.8 (3.5 to 6.6)	3.4 (2.2 to 5.2)	6.6 (4.8 to 9.0)	4.5 (2.4 to 8.8)

Year 5: hSBA-MenA(n:61, 16, 69, 21)	4.2 (3.1 to 5.9)	3.1 (2.0 to 4.8)	4.6 (3.4 to 6.2)	5.4 (2.5 to 11.7)
Year 1: hSBA-MenC(n:53, 16, 97, 24)	542.5 (284.8 to 1033.5)	230.0 (84.3 to 628.1)	427.2 (260.7 to 700.0)	234.8 (122.2 to 451.1)
Year 2: hSBA-MenC(n:59, 20, 96, 26)	368.1 (191.9 to 706.0)	223.6 (105.8 to 472.7)	342.7 (200.7 to 585.4)	169.2 (67.3 to 425.2)
Year 3: hSBA-MenC(n:64, 22, 96, 25)	378.2 (210.7 to 679.0)	203.4 (73.8 to 560.9)	365.5 (214.1 to 624.1)	273.8 (103.8 to 722.1)
Year 4: hSBA-MenC(n:63, 20, 90, 24)	319.0 (172.7 to 589.0)	217.2 (82.8 to 569.9)	190.4 (112.1 to 323.4)	125.7 (51.2 to 308.8)
Year 5: hSBA-MenC(n:62, 16, 79, 21)	362.2 (207.2 to 633.4)	112.4 (41.2 to 307.0)	199.3 (118.4 to 335.7)	119.1 (50.2 to 282.5)
Year 1: hSBA-MenW-135(n:47, 15, 92, 23)	31.8 (17.5 to 57.8)	3.3 (1.6 to 6.8)	62.5 (42.0 to 93.1)	7.0 (2.9 to 16.9)
Year 2: hSBA-MenW-135(n:58, 20, 98, 27)	19.5 (11.6 to 32.7)	4.9 (1.9 to 12.5)	50.5 (34.5 to 74.1)	4.0 (2.1 to 7.3)
Year 3: hSBA-MenW-135(n:64, 21, 94, 25)	8.0 (5.1 to 12.6)	4.1 (1.9 to 8.6)	20.4 (13.0 to 32.2)	3.3 (1.8 to 6.0)
Year 4: hSBA-MenW-135(n:58, 16, 79, 21)	8.5 (5.3 to 13.5)	3.7 (1.6 to 8.4)	23.1 (14.7 to 36.1)	2.8 (1.7 to 4.4)
Year 5: hSBA-MenW-135(n:54, 14, 67, 19)	7.6 (4.8 to 11.8)	3.8 (1.7 to 8.2)	17.4 (10.8 to 28.0)	4.2 (2.2 to 8.0)
Year 1: hSBA-MenY(n:41, 14, 89, 24)	7.9 (4.1 to 15.2)	3.1 (1.2 to 7.6)	40.3 (23.9 to 68.1)	7.3 (2.7 to 19.8)
Year 2: hSBA-MenY(n:56, 21, 100, 27)	15.8 (9.0 to 27.7)	6.9 (2.9 to 16.6)	54.4 (35.0 to 84.4)	10.5 (4.4 to 25.0)
Year 3: hSBA-MenY(n:63, 21, 93, 23)	11.6 (7.3 to 18.6)	8.7 (3.5 to 21.5)	43.7 (27.5 to 69.5)	8.8 (3.4 to 22.5)
Year 4: hSBA-MenY(n:61, 19, 84, 22)	7.3 (4.4 to 11.9)	5.8 (2.3 to 15.0)	35.5 (21.5 to 58.8)	6.2 (2.5 to 15.3)
Year 5: hSBA-MenY(n:58, 15, 73, 18)	8.6 (5.3 to 14.2)	8.5 (2.8 to 25.7)	36.8 (22.4 to 60.7)	13.9 (4.2 to 46.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 For Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With rSBA Titers >=1:8 and >=1:128 For Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination in study MenACWY-TT-027 and booster vaccination in this study (MenACWY-TT-100) and had available assay results for the 1 month post booster vaccination blood sample. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup titers cut off.

End point type	Secondary

End point timeframe:

1 month after booster vaccination (approximately Year 5.5 of study MENACWY-TT-100)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	16	74	17
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >= 1:8 (n:62, 16, 74, 17)	98.4 (91.3 to 100.0)	100.0 (79.4 to 100.0)	95.9 (88.6 to 99.2)	100.0 (80.5 to 100.0)
rSBA-MenC: >= 1:8 (n:62, 16, 74, 17)	100.0 (94.2 to 100.0)	100.0 (79.4 to 100.0)	100.0 (95.1 to 100.0)	100.0 (80.5 to 100.0)
rSBA-MenW-135: >= 1:8 (n:62, 15, 74, 17)	100.0 (94.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (95.1 to 100.0)	94.1 (71.3 to 99.9)
rSBA-MenY >= 1:8 (n:62, 16, 74, 17)	98.4 (91.3 to 100.0)	100.0 (79.4 to 100.0)	100.0 (95.1 to 100.0)	100.0 (80.5 to 100.0)
rSBA-MenA: >= 1:28 (n:62, 16, 74, 17)	98.4 (91.3 to 100.0)	100.0 (79.4 to 100.0)	95.9 (88.6 to 99.2)	100.0 (80.5 to 100.0)
rSBA-MenC: >= 1:28 (n:62, 16, 74, 17)	100.0 (94.2 to 100.0)	100.0 (79.4 to 100.0)	100.0 (95.1 to 100.0)	100.0 (80.5 to 100.0)
rSBA-MenW-135: >= 1:28 (n:62, 15, 74, 17)	100.0 (94.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (95.1 to 100.0)	94.1 (71.3 to 99.9)
rSBA-MenY >= 1:28 (n:62, 16, 74, 17)	98.4 (91.3 to 100.0)	100.0 (79.4 to 100.0)	100.0 (95.1 to 100.0)	100.0 (80.5 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Geometric Mean Titers as Measured by rSBA For Each of the 4 Serogroups 1 Month After Booster Vaccination

End point title	Booster Phase: Geometric Mean Titers as Measured by rSBA For Each of the 4 Serogroups 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination in study MenACWY-TT-027 and booster vaccination in this study (MenACWY-TT-100) and had available assay results for the 1 month post booster vaccination blood sample. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup titers cut off.

End point type	Secondary

End point timeframe:

1 month after booster vaccination (approximately Year 5.5 of study MENACWY-TT-100)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	16	74	17
Units: titers				
geometric mean (confidence interval				

95%)				
rSBA-MenA (n:62, 16, 74, 17)	5122.3 (3725.6 to 7042.6)	4871.0 (2465.1 to 9624.9)	4626.4 (3040.6 to 7039.4)	6414.2 (3878.5 to 10607.8)
rSBA-MenC (n:62, 16, 74, 17)	7163.5 (5478.0 to 9367.7)	5792.6 (3630.6 to 9242.2)	4020.0 (3319.0 to 4869.1)	15101.0 (7099.3 to 32121.5)
rSBA-MenW-135 (n:62, 15, 74, 17)	25911.2 (19119.7 to 35115.2)	17970.4 (11666.4 to 27680.7)	27944.4 (22213.8 to 35153.3)	10462.5 (3253.5 to 33645.5)
rSBA-MenY (n:62, 16, 74, 17)	7660.5 (5262.9 to 11150.3)	6316.9 (3223.8 to 12377.5)	7529.7 (5827.5 to 9729.2)	6959.2 (3636.7 to 13317.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With rSBA Booster Response at 1 Month After Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With rSBA Booster Response at 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. rSBA booster response to meningococcal antigens (A,C, W-135 and Y) is defined as: rSBA antibody titer >= 1:32 one month after vaccination, and at least 4-fold increase in rSBA titers one month after vaccination. All eligible subjects who received primary vaccination in study MenACWY-TT-027 and booster vaccination in this study (MenACWY-TT-100), had available assay results for 1 month post booster vaccination blood sample. "N": number of subjects evaluable for this measure. n": subjects analyzed for specified serogroup.

End point type	Secondary

End point timeframe:

1 month after booster vaccination (approximately Year 5.5 of study MENACWY-TT-100)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	16	74	17
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA (n=62, 16, 73, 17)	90.3 (80.1 to 96.4)	100.0 (79.4 to 100.0)	87.7 (77.9 to 94.2)	94.1 (71.3 to 99.9)
rSBA-MenC (n=62, 16, 74, 17)	82.3 (70.5 to 90.8)	93.8 (69.8 to 99.8)	75.7 (64.3 to 84.9)	94.1 (71.3 to 99.9)
rSBA-MenW-135 (n=62, 15, 74, 17)	100.0 (94.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (95.1 to 100.0)	88.2 (63.6 to 98.5)
rSBA-MenY (n=62, 16, 74, 17)	95.2 (86.5 to 99.0)	87.5 (61.7 to 98.4)	93.2 (84.9 to 97.8)	100.0 (80.5 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With hSBA Titers >=1:4 and >=1:8 For Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With hSBA Titers >=1:4 and >=1:8 For Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects: received primary vaccination in study MenACWY-TT-027, booster vaccination in study MenACWY-TT-100, had available assay results for 1 month post booster vaccination blood sample. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup titers cut off.

End point type	Secondary

End point timeframe:

1 month after booster vaccination (approximately Year 5.5 of study MENACWY-TT-100)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	16	74	17
Units: percentage of subjects				
number (confidence interval 95%)				
hSBA-MenA: >=1:4 (n=62, 16, 73, 17)	100.0 (94.2 to 100.0)	87.5 (61.7 to 98.4)	100.0 (95.1 to 100.0)	100.0 (80.5 to 100.0)
hSBA-MenC: >=1:4 (n=59, 15, 71, 17)	100.0 (93.9 to 100.0)	100.0 (78.2 to 100.0)	100.0 (94.9 to 100.0)	94.1 (71.3 to 99.9)
hSBA-MenW-135: >=1:4 (n=62, 13, 74, 15)	100.0 (94.2 to 100.0)	100.0 (75.3 to 100.0)	100.0 (95.1 to 100.0)	100.0 (78.2 to 100.0)
hSBA-MenY: >=1:4 (n=61, 15, 74, 17)	100.0 (94.1 to 100.0)	93.3 (68.1 to 99.8)	100.0 (95.1 to 100.0)	100.0 (80.5 to 100.0)
hSBA-MenA: >=1:8 (n=62, 16, 73, 17)	100.0 (94.2 to 100.0)	87.5 (61.7 to 98.4)	100.0 (95.1 to 100.0)	100.0 (80.5 to 100.0)
hSBA-MenC: >=1:8 (n=59, 15, 71, 17)	100.0 (93.9 to 100.0)	100.0 (78.2 to 100.0)	100.0 (94.9 to 100.0)	94.1 (71.3 to 99.9)
hSBA-MenW-135: >=1:8 (n=62, 13, 74, 15)	100.0 (94.2 to 100.0)	100.0 (75.3 to 100.0)	100.0 (95.1 to 100.0)	100.0 (78.2 to 100.0)
hSBA-MenY: >=1:8 (n=61, 15, 74, 17)	100.0 (94.1 to 100.0)	93.3 (68.1 to 99.8)	100.0 (95.1 to 100.0)	100.0 (80.5 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Geometric Mean Titers Using hSBA For Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point title	Booster Phase: Geometric Mean Titers Using hSBA For Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects: received primary vaccination in study MenACWY-TT-027, booster vaccination in study MenACWY-TT-100, had available assay results for 1 month post booster vaccination blood sample. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup.

End point type	Secondary

End point timeframe:

1 month after booster vaccination (approximately Year 5.5 of study MENACWY-TT-100)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	16	74	17
Units: titers				
geometric mean (confidence interval 95%)				
hSBA-MenA (n=62, 16, 73, 17)	1534.2 (1112.1 to 2116.6)	90.0 (35.7 to 227.1)	1213.0 (993.9 to 1480.5)	211.1 (130.9 to 340.3)
hSBA-MenC (n=59, 15, 71, 17)	33959.8 (23890.2 to 48273.5)	42559.2 (20106.2 to 90086.2)	15543.5 (11734.9 to 20588.3)	44794.4 (10111.6 to 198440.4)
hSBA-MenW-135 (n=62, 13, 74, 15)	11924.8 (8715.6 to 16315.7)	258.1 (155.7 to 427.8)	6965.2 (5274.3 to 9198.3)	199.6 (101.0 to 394.7)
hSBA-MenY (n=61, 15, 74, 17)	12154.3 (9660.9 to 15291.1)	407.8 (129.9 to 1280.3)	11127.4 (8909.2 to 13898.0)	453.9 (214.6 to 959.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With hSBA Booster Response at 1 Month After Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With hSBA Booster Response at 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. hSBA booster response to meningococcal antigens (A,C, W-135 and Y) is defined as: hSBA antibody titer >= 1:8 one month after vaccination, and at least 4-fold increase in hSBA titers one month after vaccination. All eligible subjects: received primary vaccination in study MenACWY-TT-027, booster vaccination in study MenACWY-TT-100, had available assay results for 1 month post booster vaccination blood sample. "N": number of subjects evaluable for this measure. "n": subjects analyzed for specified serogroup.

End point type	Secondary

End point timeframe:

1 month after booster vaccination (approximately Year 5.5 of study MENACWY-TT-100)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	15	70	17
Units: percentage of subjects				
number (confidence interval 95%)				
hSBA-MenA (n:59, 15, 61, 17)	98.3 (90.9 to 100.0)	93.3 (68.1 to 99.8)	100.0 (94.1 to 100.0)	88.2 (63.6 to 98.5)
hSBA-MenC (n:57, 14, 70, 17)	86.0 (74.2 to 93.7)	92.9 (66.1 to 99.8)	85.7 (75.3 to 92.9)	94.1 (71.3 to 99.9)
hSBA-MenW-135 (n:52, 11, 59, 14)	100.0 (93.2 to 100.0)	90.9 (58.7 to 99.8)	96.6 (88.3 to 99.6)	100.0 (76.8 to 100.0)
hSBA-MenY (n:56, 14, 65, 14)	100.0 (93.6 to 100.0)	71.4 (41.9 to 91.6)	98.5 (91.7 to 100.0)	78.6 (49.2 to 95.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Persistence Phase: Percentage of Subjects With Serious Adverse Events (SAEs) Related to Vaccination or Any Adverse Event Related to Lack of Vaccine Efficacy

End point title	Persistence Phase: Percentage of Subjects With Serious Adverse Events (SAEs) Related to Vaccination or Any Adverse Event Related to Lack of Vaccine Efficacy

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. AEs related to "lack of vaccine efficacy" were as judged by the investigator. All the subjects enrolled in the study.

End point type	Secondary

End point timeframe:

Through 5 years (6, 7, 8, 9 and 10 years post primary vaccination)

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	76	23	115	29
Units: percentage of subjects				
number (not applicable)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Solicited Local and General Adverse Events up to 4 Days Post Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With Solicited Local and General Adverse Events up to 4 Days Post Booster Vaccination

End point description:

Solicited general events: fatigue, GI events (nausea, vomiting, diarrhea and/or abdominal pain, headache (0= normal, 1=mild/easily tolerated, 2=moderate/interfered with normal activity, 3=severe/prevented normal activity) and fever (>=37.5°C for oral/axillary/tympanic route, >=38.0°C for rectal route). Solicited local events: pain (0=none, 1=mild, not interfered/prevented normal activity, 2=moderate, painful when limb moved/interfered with normal activity, 3=severe, significant pain at rest/prevented normal activity), redness and swelling at injection site (record greatest surface diameter in mm as 0 to <=20 mm, >20 to <=50 mm, >50 mm). Subjects may be represented in more than 1 category. Only categories with at least 1 subject reported. 'Medical advice' signifies medical advice received to resolve any event. 'Related'=relationship to study vaccine assessed by investigator. Subjects who received a booster dose of study vaccine MenACWY-TT. n=subjects analyzed for specified category.

End point type	Secondary

End point timeframe:

Up to 4 days post booster vaccination

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	16	77	21
Units: percentage of subjects				
number (not applicable)				
All pain(n: 67, 16, 74, 21)	59.7	56.3	59.5	61.9
Pain: Grade 1(n: 67, 16, 74, 21)	43.3	37.5	40.5	42.9
Pain: Grade 2(n: 67, 16, 74, 21)	16.4	18.8	16.2	19.0
Severe Pain: Grade 3(n: 67, 16, 74, 21)	0	0	0	0
All redness(n: 67, 16, 74, 21)	35.8	43.8	36.5	23.8
Redness: 0 to <=20 mm (n: 67, 16, 74, 21)	28.4	25.0	31.1	14.3
Redness: >20 to <=50 mm(n: 67, 16, 74, 21)	1.5	18.8	2.7	0.0
Redness: >50 mm(n: 67, 16, 74, 21)	6.0	0	2.7	9.5

All swelling(n: 67, 16, 77, 21)	17.9	6.3	23.0	14.3
Swelling: 0 to <=20 mm(n: 67, 16, 74, 21)	14.9	0	16.2	0.0
Swelling: >20 to <=50 mm(n: 67, 16, 74, 21)	1.5	6.3	1.4	4.8
Swelling: >50 mm(n: 67, 16, 74, 21)	1.5	0.0	5.4	9.5
All fatigue(n: 67, 16, 74, 21)	31.3	12.5	29.7	23.8
Fatigue: Grade 1(n: 67, 16, 74, 21)	20.9	12.5	16.2	14.3
Fatigue: Grade 2(n: 67, 16, 74, 21)	9.0	0.0	6.8	9.5
Fatigue: Grade 3(n: 67, 16, 74, 21)	1.5	0.0	6.8	0.0
Fatigue: Related fatigue(n: 67, 16, 74, 21)	31.3	12.5	29.7	23.8
Fatigue: Grade 3 Related(n: 67, 16, 74, 21)	1.5	0.0	6.8	0.0
All fever(n: 67, 16, 74, 21)	1.5	0.0	0.0	0.0
Fever: Grade 1(n: 67, 16, 74, 21)	1.5	0.0	0.0	0.0
Fever: Grade 2(n: 67, 16, 74, 21)	0.0	0.0	0.0	0.0
Fever: Grade 3(n: 67, 16, 74, 21)	0.0	0.0	0.0	0.0
Fever: Related(n: 67, 16, 74, 21)	1.5	0.0	0.0	0.0
Fever: Grade 3 related(n: 67, 16, 74, 21)	0.0	0.0	0.0	0.0
All gastrointestinal event(GI)(n: 67, 16, 74, 21)	9.0	0.0	17.6	14.3
GI: Grade 1(n: 67, 16, 74, 21)	7.5	0.0	13.5	4.8
GI: Grade 2(n: 67, 16, 74, 21)	1.5	0.0	2.7	9.5
GI: Grade 3(n: 67, 16, 74, 21)	0.0	0.0	1.4	0.0
GI: Related(n: 67, 16, 74, 21)	7.5	0.0	17.6	14.3
GI: Grade 3 related(n: 67, 16, 74, 21)	0.0	0.0	1.4	0.0
All headache(n: 67, 16, 74, 21)	20.9	31.3	27.0	23.8
Headache: Grade 1(n: 67, 16, 74, 21)	14.9	18.8	18.9	19.0
Headache: Grade 2(n: 67, 16, 74, 21)	6.0	12.5	6.8	4.8
Headache: Grade 3(n: 67, 16, 74, 21)	0.0	0.0	0.0	0.0
Headache: Related(n: 67, 16, 74, 21)	17.9	31.3	24.3	23.8
Headache: Grade 3 related(n: 67, 16, 74, 21)	0.0	0.0	1.4	0.0
Headache: Medical advice(n: 67, 16, 74, 21)	0.0	0.0	1.4	0.0

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Unsolicited Adverse Events up to 31 Days Post Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With Unsolicited Adverse Events up to 31 Days Post Booster Vaccination

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Analysis population included all subjects who received a booster dose of study vaccine MenACWY-TT in the booster stage.

End point type	Secondary

End point timeframe:

Up to 31 days post booster vaccination

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	16	77	21
Units: percentage of subjects				
number (not applicable)	23.9	31.3	35.1	52.4

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Serious Adverse Events (SAEs) Up to 6 Months Post Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With Serious Adverse Events (SAEs) Up to 6 Months Post Booster Vaccination

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Analysis population included all subjects who received a booster dose of study vaccine MenACWY-TT in the booster stage.

End point type	Secondary

End point timeframe:

Up to 6 months post booster vaccination

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	16	77	21
Units: percentage of subjects				
number (not applicable)	0.0	0.0	1.3	0.0

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With New Onset Chronic Illness Up to 6 Months Post Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With New Onset Chronic Illness Up to 6 Months Post Booster Vaccination

End point description:

New onset chronic illness included autoimmune disorders, asthma, type I diabetes, allergies. Analysis population included all subjects who received a booster dose of study vaccine MenACWY-TT in the booster stage.

End point type	Secondary

End point timeframe:

Up to 6 months post booster vaccination

End point values	MenACWY-TT Vaccine (Less Than [<] 2 Years)	MenCCRM (Meningitec) Vaccine(<2 Years)	MenACWY-TT Vaccine(Greater Than or Equal to [>=] 2 Years)	MenPS (Mencevax ACWY) Vaccine (< 2 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	16	77	21
Units: percentage of subjects				
number (not applicable)	0.0	0.0	1.3	4.8

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

For persistence phase: Through 5 years (6, 7, 8, 9 and 10 years post primary vaccination); Booster phase: up to 6 months after booster vaccination

Adverse event reporting additional description:

Same event may appear as both an AE and SAE. 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 subject may have experienced both a serious and non-serious event.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Persistence Phase: MenACWY-TT Vaccine (<2 Years)

Reporting group description:

Subjects with <2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100), they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination).

Reporting group title	Persistence Phase:MenCCRM (Meningitec) Vaccine(<2 Years)

Reporting group description:

Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination).

Reporting group title	Persistence Phase: MenACWY-TT Vaccine (>=2 Years)

Reporting group description:

Subjects with >=2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination).

Reporting group title	Persistence Phase:MenPS (Mencevax ACWY) Vaccine (<2 Years)

Reporting group description:

Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination).

Reporting group title	Booster Phase: MenACWY-TT Vaccine (<2 Years)

Reporting group description:

Persistence phase: Subjects with <2 years of age, received a single 0.5mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100), they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in MENACWY-TT-027, and were followed up for 6 months after booster vaccination.

Reporting group title	Booster Phase: MenCCRM (Meningitec) Vaccine (<2 Years)

Reporting group description:

Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of Meningitec vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Reporting group title	Booster Phase: MenACWY-TT Vaccine (>= 2 Years)

Reporting group description:

Persistence phase: Subjects with >=2 years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long-term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Reporting group title	Booster Phase: MenPS (Mencevax ACWY) Vaccine (<2 Years)

Reporting group description:

Persistence phase: Subjects with <2 years of age, received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027. Then, in this study (MENACWY-TT-100) they were evaluated for long term persistence (of immune response and safety) for 5 years (6, 7, 8, 9 and 10 years post primary vaccination). Booster phase: Subjects who provided consent, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Serious adverse events	Persistence Phase: MenACWY-TT Vaccine (<2 Years)	Persistence Phase:MenCCRM (Meningitec) Vaccine(<2 Years)	Persistence Phase: MenACWY-TT Vaccine (>=2 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Persistence Phase:MenPS (Mencevax ACWY) Vaccine (<2 Years)	Booster Phase: MenACWY-TT Vaccine (<2 Years)	Booster Phase: MenCCRM (Meningitec) Vaccine (<2 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Booster Phase: MenACWY-TT Vaccine (>= 2 Years)	Booster Phase: MenPS (Mencevax ACWY) Vaccine (<2 Years)	

Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Persistence Phase: MenACWY-TT Vaccine (<2 Years)	Persistence Phase:MenCCRM (Meningitec) Vaccine(<2 Years)	Persistence Phase: MenACWY-TT Vaccine (>=2 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
Injury, poisoning and procedural complications			
Foot fracture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0

Oropharyngeal pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Headache 1			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)

occurrences (all)	0	0	0

General disorders and administration site conditions			
Axillary pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Fatigue 1			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (redness)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Injection site pain (pain at injection site)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (swelling)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0

Pyrexia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Coeliac disease			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal symptoms			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle tightness			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)

occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 76 (0.00%)	0 / 23 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Persistence Phase:MenPS (Mencevax ACWY) Vaccine (<2 Years)	Booster Phase: MenACWY-TT Vaccine (<2 Years)	Booster Phase: MenCCRM (Meningitec) Vaccine (<2 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 29 (0.00%)	53 / 67 (79.10%)	12 / 16 (75.00%)
Injury, poisoning and procedural complications			
Foot fracture			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hand fracture			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Oropharyngeal pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Throat irritation			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Headache 1			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 29 (0.00%)	14 / 67 (20.90%)	5 / 16 (31.25%)
occurrences (all)	0	19	7
Headache			
subjects affected / exposed	0 / 29 (0.00%)	4 / 67 (5.97%)	1 / 16 (6.25%)
occurrences (all)	0	5	1
Hypoaesthesia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)

occurrences (all)	0	1	0

General disorders and administration site conditions			
Axillary pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Fatigue 1			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 29 (0.00%)	21 / 67 (31.34%)	2 / 16 (12.50%)
occurrences (all)	0	31	4
Fatigue			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Injection site bruising			
subjects affected / exposed	0 / 29 (0.00%)	2 / 67 (2.99%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Injection site erythema (redness)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 29 (0.00%)	24 / 67 (35.82%)	7 / 16 (43.75%)
occurrences (all)	0	41	15
Injection site hypoaesthesia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injection site pain (pain at injection site)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 29 (0.00%)	40 / 67 (59.70%)	9 / 16 (56.25%)
occurrences (all)	0	72	18
Injection site pruritus			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Injection site swelling (swelling)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 29 (0.00%)	12 / 67 (17.91%)	1 / 16 (6.25%)
occurrences (all)	0	27	3

Pyrexia			
subjects affected / exposed	0 / 29 (0.00%)	2 / 67 (2.99%)	2 / 16 (12.50%)
occurrences (all)	0	2	2
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Coeliac disease			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal symptoms			
subjects affected / exposed	0 / 29 (0.00%)	6 / 67 (8.96%)	0 / 16 (0.00%)
occurrences (all)	0	6	0
Vomiting			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle tightness			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)

occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 29 (0.00%)	2 / 67 (2.99%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Sinusitis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 67 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 29 (0.00%)	1 / 67 (1.49%)	1 / 16 (6.25%)
occurrences (all)	0	1	1

Non-serious adverse events	Booster Phase: MenACWY-TT Vaccine (>= 2 Years)	Booster Phase: MenPS (Mencevax ACWY) Vaccine (<2 Years)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 77 (84.42%)	15 / 21 (71.43%)	
Injury, poisoning and procedural complications			
Foot fracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hand fracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Joint dislocation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Nasal congestion			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	

Oropharyngeal pain			
subjects affected / exposed	2 / 77 (2.60%)	0 / 21 (0.00%)	
occurrences (all)	2	0	
Throat irritation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Lymphadenitis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Headache 1			
alternative assessment type: Systematic			
subjects affected / exposed	20 / 77 (25.97%)	5 / 21 (23.81%)	
occurrences (all)	34	9	
Headache			
subjects affected / exposed	3 / 77 (3.90%)	0 / 21 (0.00%)	
occurrences (all)	4	0	
Hypoaesthesia			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Migraine			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	2	
Paraesthesia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	

occurrences (all)	0	0	

General disorders and administration site conditions			
Axillary pain			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Fatigue 1			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 77 (28.57%)	5 / 21 (23.81%)	
occurrences (all)	48	8	
Fatigue			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	0	
Injection site bruising			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Injection site erythema (redness)			
alternative assessment type: Systematic			
subjects affected / exposed	27 / 77 (35.06%)	5 / 21 (23.81%)	
occurrences (all)	61	11	
Injection site hypoaesthesia			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Injection site pain (pain at injection site)			
alternative assessment type: Systematic			
subjects affected / exposed	44 / 77 (57.14%)	13 / 21 (61.90%)	
occurrences (all)	80	25	
Injection site pruritus			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Injection site swelling (swelling)			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 77 (22.08%)	3 / 21 (14.29%)	
occurrences (all)	39	10	

Pyrexia			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Sleep disorder			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Coeliac disease			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Gastrointestinal symptoms			
subjects affected / exposed	13 / 77 (16.88%)	3 / 21 (14.29%)	
occurrences (all)	21	7	
Vomiting			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	2 / 77 (2.60%)	0 / 21 (0.00%)	
occurrences (all)	2	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Muscle tightness			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal pain			
subjects affected / exposed	1 / 77 (1.30%)	1 / 21 (4.76%)	

occurrences (all)	1	1	
Neck pain			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis			
subjects affected / exposed	2 / 77 (2.60%)	1 / 21 (4.76%)	
occurrences (all)	2	1	
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Infectious mononucleosis			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	1 / 77 (1.30%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Otitis media			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Respiratory tract infection			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Rhinitis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Sinusitis			

subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Skin infection			
subjects affected / exposed	0 / 77 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Tonsillitis			
subjects affected / exposed	1 / 77 (1.30%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	7 / 77 (9.09%)	2 / 21 (9.52%)	
occurrences (all)	7	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 February 2016	1. Sponsor name updated throughout the protocol to Pfizer. 2. Blood sample volume increased to 10 mL for pre- and post-booster samples
25 February 2016	1. Blood sample volume increased to 10 mL for visit 4. 2. Initial pregnancy reporting and follow-up reports were updated to 24 hours and updated to indicate that paper SAE and EDP (exposure during pregnancy) reports were to be submitted for pregnancies. reports will be submitted for pregnancies.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported