

**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 ( $\geq$ )1:8,  $\geq$ 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  $\geq$ 1:8,  $\geq$ 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  $\geq$ 1:8,  $\geq$ 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  |
| <b>Arm title</b>             | 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.

|                  |   |
|------------------|---|
| <b>Arm title</b> | 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.

|  |   |
|--|---|
| <b>Arm title</b>   | MenACWY-TT Vaccine(Greater Than or Equal to [ $\geq$ ] 2 Years) |
| Arm description:   |   |
| Persistence phase was followed up by booster phase. Persistence phase: Subjects with $\geq 2$ 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 $\geq 2$ years of age, received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study MENACWY-TT-027.  |   |
| <b>Arm title</b>   | 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 [ $\geq$ ] 2 Years) |
|-------------------------------------|--|--|---|
|                                     |  |  |   |
| Started                             | 76   | 23                                     | 115   |
| Completed                           | 47   | 10                                     | 71  |
| Not completed                       | 29   | 13                                     | 44  |
| Consent withdrawn by subject        | 4  | 5                                      | 18  |
| Eligibility criteria not fulfilled  | -  | -                                      | 3   |
| Adverse event, non-fatal            | -  | -                                      | 1   |
| Migrated/moved from study area      | 2  | -                                      | 4   |
| Lost to follow-up                   | 2  | 1                                      | 5   |
| Missed at least 1 persistence visit | 21   | 7                                      | 13  |

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| Consent withdrawn by subject        | 4   |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

## 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  |
| <b>Arm title</b>             | 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.

|                  |   |
|------------------|---|
| <b>Arm title</b> | 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.

|                  |   |
|------------------|---|
| <b>Arm title</b> | MenACWY-TT Vaccine: Greater Than or Equal to ( $\geq$ ) 2 Years |
|------------------|---|

**Arm description:**

Persistence phase was followed up by booster phase. Persistence phase: Subjects with  $\geq 2$  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  $\geq 2$  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.

|                  |  |
|------------------|--|
| <b>Arm title</b> | 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<br>Vaccine: Less Than<br>( $<$ ) 2 Years | MenCCRM<br>(Meningitec)<br>Vaccine: Less Than 2<br>Years | MenACWY-TT<br>Vaccine: Greater<br>Than or Equal to<br>( $\geq$ ) 2 Years |
|--------------------------------|---|--|--|
|                                |   |  |  |
| Started                        | 67  | 16   | 77   |
| Completed                      | 67  | 16   | 77   |

| Number of subjects in period 2 | MenPS (Mencevax<br>ACWY) Vaccine:<br>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 [ $\geq$ ] 2 Years) |
| Reporting group description:  |   |
| Persistence phase was followed up by booster phase. Persistence phase: Subjects with $\geq 2$ 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 [ $\geq$ ] 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<br>Units: years<br>arithmetic mean<br>standard deviation | 8.2<br>± 0.7 | 8.2<br>± 0.7 | 12.5<br>± 2.6 |
| Sex: Female, Male<br>Units: Subjects                                    |              |              |               |
| Female  | 40           | 12           | 56            |
| Male  | 36           | 11           | 59            |
| Race/Ethnicity, Customized<br>Units: Subjects                           |              |              |               |
| White - Arabic/North African heritage                                   | 0            | 0            | 1             |
| White - Caucasian/European heritage                                     | 75           | 22           | 113           |
| Other   | 1            | 1            | 1             |
| Ethnicity (NIH/OMB)<br>Units: Subjects                                  |              |              |               |
| Hispanic or Latino  | 0            | 0            | 0             |
| Not Hispanic or Latino  | 76           | 23           | 115           |
| Unknown or Not Reported   | 0            | 0            | 0             |

| <b>Reporting group values</b>   | MenPS (Mencevax ACWY) Vaccine (< 2 Years) | Total |  |
|---|---|-------|--|
| Number of subjects  | 29  | 243   |  |
| Age categorical<br>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<br>Units: years<br>arithmetic mean<br>standard deviation | 12.1<br>± 2.9                             | -     |  |
| Sex: Female, Male<br>Units: Subjects                                    |   |       |  |
| Female  | 14  | 122   |  |
| Male  | 15  | 121   |  |
| Race/Ethnicity, Customized<br>Units: Subjects                           |   |       |  |
| White - Arabic/North African heritage                                   | 0   | 1     |  |

|  |    |     |  |
|--|----|-----|--|
| White - Caucasian/European<br>heritage | 28 | 238 |  |
| Other                                  | 1  | 4   |  |
| Ethnicity (NIH/OMB)<br>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 [ $\geq$ ] 2 Years) |
|-----------------------|---|

#### Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with  $\geq 2$  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 ( $\geq$ ) 2 Years |
|-----------------------|---|

#### Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects with  $\geq 2$  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 $\geq 1:8$ and $\geq 1:128$ 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 $\geq 1:8$ and $\geq 1:128$ For Each of the 4 Serogroups After 6 Years of Primary Vaccination <sup>[1]</sup> |
|-----------------|--|

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 [ $\geq$ ] 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: $\geq 1:8$            | 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: $\geq 1:8$            | 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: $\geq 1:8$        | 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: $\geq 1:8$            | 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: $\geq 1:28$           | 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: $\geq 1:28$           | 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: $\geq 1:28$ | 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: $\geq 1:28$     | 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 $\geq 1:8$ and $\geq 1:128$ For Each of the 4 Serogroups After 7 Years of Primary Vaccination

|                 |   |
|-----------------|---|
| End point title | Persistence Phase: Percentage of Subjects With rSBA Titers $\geq 1:8$ and $\geq 1:128$ For Each of the 4 Serogroups After 7 Years of Primary Vaccination <sup>[2]</sup> |
|-----------------|---|

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 [ $\geq$ ] 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: $\geq 1:8$ (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: $\geq 1:8$ (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: $\geq 1:8$ (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: $\geq 1:8$ (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: $\geq 1:28$ (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: $\geq 1:28$ (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: $\geq 1:28$ (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: $\geq 1:28$ (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 $\geq 1:8$ and $\geq 1:128$ For Each of the 4 Serogroups After 8 Years of Primary Vaccination

|                 |   |
|-----------------|---|
| End point title | Persistence Phase: Percentage of Subjects With rSBA Titers $\geq 1:8$ and $\geq 1:128$ For Each of the 4 Serogroups After 8 Years of Primary Vaccination <sup>[3]</sup> |
|-----------------|---|

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 [ $\geq$ ] 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: $\geq 1:8$            | 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: $\geq 1:8$            | 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: $\geq 1:8$        | 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: $\geq 1:8$            | 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: $\geq 1:128$          | 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: $\geq 1:128$          | 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: $\geq 1:128$      | 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: $\geq 1:128$          | 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 $\geq 1:8$ and $\geq 1:128$ For Each of the 4 Serogroups After 9 Years of Primary Vaccination

|                 |   |
|-----------------|---|
| End point title | Persistence Phase: Percentage of Subjects With rSBA Titers $\geq 1:8$ and $\geq 1:128$ For Each of the 4 Serogroups After 9 Years of Primary Vaccination <sup>[4]</sup> |
|-----------------|---|

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 [ $\geq$ ] 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 $\geq$ 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 $\geq$ 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 $\geq$ 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 $\geq$ 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 $\geq$ 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 $\geq$ 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 $\geq$ 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 $\geq$ 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 $\geq$ 1:8 and $\geq$ 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 $\geq$ 1:8 and $\geq$ 1:128 For Each of the 4 Serogroups After 10 Years of Primary Vaccination <sup>[5]</sup> |
|-----------------|--|

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 [ $\geq$ ] 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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:28$ (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 $\geq 1:28$ (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 $\geq 1:28$ (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 $\geq 1:28$ (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 <sup>[6]</sup> |
|-----------------|---|

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 [ $\geq$ ] 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 <sup>[7]</sup> |
|-----------------|---|

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 [ $\geq$ ] 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 <sup>[8]</sup> |
|-----------------|---|

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 [ $\geq$ ] 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 |
|-----------------|--|

## 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 [ $\geq$ ] 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 <sup>[10]</sup> |
|-----------------|---|

## 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 [ $\geq$ ] 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 $\geq 1:4$ and $\geq 1:8$ 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 $\geq 1:4$ and $\geq 1:8$ 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 [ $\geq$ ] 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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:4$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 $\geq 1:8$ (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 [ $\geq$ ] 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 $\geq 1:8$ and $\geq 1:128$ For Each of the 4 Serogroups at 1 Month After Booster Vaccination

|                 |  |
|-----------------|--|
| End point title | Booster Phase: Percentage of Subjects With rSBA Titers $\geq 1:8$ and $\geq 1:128$ 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 [ $\geq$ ] 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: $\geq 1:8$ (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: $\geq 1:8$ (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: $\geq 1:8$ (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 $\geq 1:8$ (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: $\geq 1:28$ (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: $\geq 1:28$ (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: $\geq 1:28$ (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 $\geq 1:28$ (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 [ $\geq$ ] 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:<br>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 $\geq 1:32$ 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:<br>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 [ $\geq$ ] 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 $\geq 1:4$ and $\geq 1:8$ For Each of the 4 Serogroups at 1 Month After Booster Vaccination

|                 |  |
|-----------------|--|
| End point title | Booster Phase: Percentage of Subjects With hSBA Titers $\geq 1:4$ and $\geq 1:8$ 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 [ $\geq$ ] 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: $\geq 1:4$ (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: $\geq 1:4$ (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: $\geq 1:4$ (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: $\geq 1:4$ (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: $\geq 1:8$ (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: $\geq 1:8$ (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: $\geq 1:8$ (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: $\geq 1:8$ (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

## 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 [ $\geq$ ] 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  $\geq$  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 [ $\geq$ ] 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 [ $\geq$ ] 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 ( $\geq 37.5^{\circ}\text{C}$  for oral/axillary/tympanic route,  $\geq 38.0^{\circ}\text{C}$  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  $\leq 20$  mm,  $>20$  to  $\leq 50$  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 [ $\geq$ ] 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 $\leq 20$ mm (n: 67, 16, 74, 21)    | 28.4   | 25.0                                       | 31.1  | 14.3                                      |
| Redness: $>20$ to $\leq 50$ 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 [ $\geq$ ] 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 [ $\geq$ ] 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

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

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|                 |  |
|-----------------|--|
| 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 [ $\geq$ ] 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  |

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**Statistical analyses**

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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 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  $\geq 2$  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:<br>MenACWY-TT<br>Vaccine (<2 Years) | Persistence<br>Phase: MenCCRM<br>(Meningitec)<br>Vaccine (<2 Years) | Persistence Phase:<br>MenACWY-TT<br>Vaccine ( $\geq 2$ 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<br>Phase: MenPS<br>(Mencevax ACWY)<br>Vaccine (<2 Years) | Booster Phase:<br>MenACWY-TT<br>Vaccine (<2 Years) | Booster Phase:<br>MenCCRM<br>(Meningitec) Vaccine<br>(<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:<br>MenACWY-TT<br>Vaccine ( $\geq 2$<br>Years) | Booster Phase:<br>MenPS (Mencevax<br>ACWY) Vaccine (<2<br>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 %

| <b>Non-serious adverse events</b>                     | Persistence Phase:<br>MenACWY-TT<br>Vaccine (<2 Years) | Persistence Phase: MenCCRM<br>(Meningitec)<br>Vaccine(<2 Years) | Persistence Phase:<br>MenACWY-TT<br>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   |
| 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:<br>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<br>occurrences (all)   | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Hypoaesthesia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Migraine<br>subjects affected / exposed<br>occurrences (all)   | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Blood and lymphatic system disorders<br>Lymph node pain<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Lymphadenitis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| General disorders and administration<br>site conditions<br>Axillary pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Fatigue 1<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)  | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Injection site bruising<br>subjects affected / exposed<br>occurrences (all)  | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Injection site erythema (redness)<br>alternative assessment type:<br>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               |
| 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               |
| 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<br>occurrences (all)  | 0 / 76 (0.00%)<br>0  | 0 / 23 (0.00%)<br>0  | 0 / 115 (0.00%)<br>0   |
| Reproductive system and breast disorders<br>Dysmenorrhoea<br>subjects affected / exposed<br>occurrences (all)   | 0 / 76 (0.00%)<br>0  | 0 / 23 (0.00%)<br>0  | 0 / 115 (0.00%)<br>0   |
| Respiratory, thoracic and mediastinal disorders<br>Asthma<br>subjects affected / exposed<br>occurrences (all)<br><br>Cough<br>subjects affected / exposed<br>occurrences (all)<br><br>Nasal congestion<br>subjects affected / exposed<br>occurrences (all)<br><br>Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Throat irritation<br>subjects affected / exposed<br>occurrences (all) | 0 / 76 (0.00%)<br>0<br><br>0 / 76 (0.00%)<br>0<br><br>0 / 76 (0.00%)<br>0<br><br>0 / 76 (0.00%)<br>0<br><br>0 / 76 (0.00%)<br>0<br><br>0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0<br><br>0 / 23 (0.00%)<br>0<br><br>0 / 23 (0.00%)<br>0<br><br>0 / 23 (0.00%)<br>0<br><br>0 / 23 (0.00%)<br>0<br><br>0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0<br><br>0 / 115 (0.00%)<br>0<br><br>0 / 115 (0.00%)<br>0<br><br>0 / 115 (0.00%)<br>0<br><br>0 / 115 (0.00%)<br>0<br><br>0 / 115 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>Acne<br>subjects affected / exposed<br>occurrences (all)  | 0 / 76 (0.00%)<br>0  | 0 / 23 (0.00%)<br>0  | 0 / 115 (0.00%)<br>0   |
| Psychiatric disorders<br>Insomnia<br>subjects affected / exposed<br>occurrences (all)<br><br>Sleep disorder<br>subjects affected / exposed<br>occurrences (all)   | 0 / 76 (0.00%)<br>0<br><br>0 / 76 (0.00%)<br>0   | 0 / 23 (0.00%)<br>0<br><br>0 / 23 (0.00%)<br>0   | 0 / 115 (0.00%)<br>0<br><br>0 / 115 (0.00%)<br>0   |
| Musculoskeletal and connective tissue disorders   |  |  |  |

|   |                     |                     |                      |
|---|---------------------|---------------------|----------------------|
| Muscle tightness<br>subjects affected / exposed<br>occurrences (all)            | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all)        | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Neck pain<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Pain in extremity<br>subjects affected / exposed<br>occurrences (all)           | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Infections and infestations   |                     |                     |                      |
| Conjunctivitis<br>subjects affected / exposed<br>occurrences (all)              | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Ear infection<br>subjects affected / exposed<br>occurrences (all)               | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Gastroenteritis<br>subjects affected / exposed<br>occurrences (all)             | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Hand-foot-and-mouth disease<br>subjects affected / exposed<br>occurrences (all) | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Infectious mononucleosis<br>subjects affected / exposed<br>occurrences (all)    | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)             | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>0 |
| Otitis media<br>subjects affected / exposed<br>occurrences (all)                | 0 / 76 (0.00%)<br>0 | 0 / 23 (0.00%)<br>0 | 0 / 115 (0.00%)<br>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               |

| <b>Non-serious adverse events</b>                     | 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  |
| 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<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 29 (0.00%)<br>0 | 14 / 67 (20.90%)<br>19 | 5 / 16 (31.25%)<br>7 |
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 0 / 29 (0.00%)<br>0 | 4 / 67 (5.97%)<br>5    | 1 / 16 (6.25%)<br>1  |
| Hypoaesthesia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0    | 0 / 16 (0.00%)<br>0  |
| Migraine<br>subjects affected / exposed<br>occurrences (all)   | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0    | 0 / 16 (0.00%)<br>0  |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 29 (0.00%)<br>0 | 1 / 67 (1.49%)<br>1    | 0 / 16 (0.00%)<br>0  |
| Blood and lymphatic system disorders<br>Lymph node pain<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0    | 0 / 16 (0.00%)<br>0  |
| Lymphadenitis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0    | 0 / 16 (0.00%)<br>0  |
| General disorders and administration<br>site conditions<br>Axillary pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 29 (0.00%)<br>0 | 1 / 67 (1.49%)<br>1    | 0 / 16 (0.00%)<br>0  |
| Fatigue 1<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 29 (0.00%)<br>0 | 21 / 67 (31.34%)<br>31 | 2 / 16 (12.50%)<br>4 |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)  | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0    | 1 / 16 (6.25%)<br>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:<br>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:<br>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:<br>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               |
| 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               |
| 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<br>occurrences (all)  | 0 / 29 (0.00%)<br>0 | 6 / 67 (8.96%)<br>6 | 0 / 16 (0.00%)<br>0 |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)  | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0 |
| Reproductive system and breast disorders<br>Dysmenorrhoea<br>subjects affected / exposed<br>occurrences (all) | 0 / 29 (0.00%)<br>0 | 1 / 67 (1.49%)<br>1 | 0 / 16 (0.00%)<br>0 |
| Respiratory, thoracic and mediastinal disorders<br>Asthma<br>subjects affected / exposed<br>occurrences (all) | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0 |
| Cough<br>subjects affected / exposed<br>occurrences (all)   | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0 |
| Nasal congestion<br>subjects affected / exposed<br>occurrences (all)  | 0 / 29 (0.00%)<br>0 | 1 / 67 (1.49%)<br>1 | 0 / 16 (0.00%)<br>0 |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)  | 0 / 29 (0.00%)<br>0 | 1 / 67 (1.49%)<br>1 | 0 / 16 (0.00%)<br>0 |
| Throat irritation<br>subjects affected / exposed<br>occurrences (all)   | 0 / 29 (0.00%)<br>0 | 1 / 67 (1.49%)<br>1 | 0 / 16 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>Acne<br>subjects affected / exposed<br>occurrences (all)            | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0 |
| Psychiatric disorders<br>Insomnia<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0 |
| Sleep disorder<br>subjects affected / exposed<br>occurrences (all)  | 0 / 29 (0.00%)<br>0 | 0 / 67 (0.00%)<br>0 | 0 / 16 (0.00%)<br>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              |

| <b>Non-serious adverse events</b>                     | Booster Phase:<br>MenACWY-TT<br>Vaccine ( $\geq 2$<br>Years) | Booster Phase:<br>MenPS (Mencevax<br>ACWY) Vaccine ( $< 2$<br>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  |  |
| Nervous system disorders                              |  |  |  |
| Dizziness   |  |  |  |
| subjects affected / exposed                           | 0 / 77 (0.00%)   | 0 / 21 (0.00%)   |  |
| occurrences (all)                                     | 0  | 0  |  |

|  |                        |                      |  |
|--|------------------------|----------------------|--|
| Headache 1<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                 | 20 / 77 (25.97%)<br>34 | 5 / 21 (23.81%)<br>9 |  |
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 3 / 77 (3.90%)<br>4    | 0 / 21 (0.00%)<br>0  |  |
| Hypoaesthesia<br>subjects affected / exposed<br>occurrences (all)  | 1 / 77 (1.30%)<br>1    | 0 / 21 (0.00%)<br>0  |  |
| Migraine<br>subjects affected / exposed<br>occurrences (all)   | 0 / 77 (0.00%)<br>0    | 1 / 21 (4.76%)<br>2  |  |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 77 (0.00%)<br>0    | 0 / 21 (0.00%)<br>0  |  |
| Blood and lymphatic system disorders<br>Lymph node pain<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 77 (1.30%)<br>1    | 0 / 21 (0.00%)<br>0  |  |
| Lymphadenitis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 77 (0.00%)<br>0    | 1 / 21 (4.76%)<br>1  |  |
| General disorders and administration<br>site conditions<br>Axillary pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 77 (0.00%)<br>0    | 1 / 21 (4.76%)<br>1  |  |
| Fatigue 1<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                  | 22 / 77 (28.57%)<br>48 | 5 / 21 (23.81%)<br>8 |  |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)  | 0 / 77 (0.00%)<br>0    | 1 / 21 (4.76%)<br>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:<br>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:<br>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:<br>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                |  |
| Immune system disorders                      |                  |                  |  |
| Drug hypersensitivity                        |                  |                  |  |
| subjects affected / exposed                  | 1 / 77 (1.30%)   | 0 / 21 (0.00%)   |  |
| occurrences (all)                            | 1                | 0                |  |
| 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<br>occurrences (all)  | 13 / 77 (16.88%)<br>21 | 3 / 21 (14.29%)<br>7 |  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)  | 1 / 77 (1.30%)<br>1    | 0 / 21 (0.00%)<br>0  |  |
| Reproductive system and breast disorders<br>Dysmenorrhoea<br>subjects affected / exposed<br>occurrences (all) | 2 / 77 (2.60%)<br>2    | 0 / 21 (0.00%)<br>0  |  |
| Respiratory, thoracic and mediastinal disorders<br>Asthma<br>subjects affected / exposed<br>occurrences (all) | 1 / 77 (1.30%)<br>1    | 0 / 21 (0.00%)<br>0  |  |
| Cough<br>subjects affected / exposed<br>occurrences (all)   | 1 / 77 (1.30%)<br>1    | 0 / 21 (0.00%)<br>0  |  |
| Nasal congestion<br>subjects affected / exposed<br>occurrences (all)  | 0 / 77 (0.00%)<br>0    | 0 / 21 (0.00%)<br>0  |  |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)  | 2 / 77 (2.60%)<br>2    | 0 / 21 (0.00%)<br>0  |  |
| Throat irritation<br>subjects affected / exposed<br>occurrences (all)   | 0 / 77 (0.00%)<br>0    | 0 / 21 (0.00%)<br>0  |  |
| Skin and subcutaneous tissue disorders<br>Acne<br>subjects affected / exposed<br>occurrences (all)            | 1 / 77 (1.30%)<br>1    | 0 / 21 (0.00%)<br>0  |  |
| Psychiatric disorders<br>Insomnia<br>subjects affected / exposed<br>occurrences (all)                         | 1 / 77 (1.30%)<br>1    | 0 / 21 (0.00%)<br>0  |  |
| Sleep disorder<br>subjects affected / exposed<br>occurrences (all)  | 0 / 77 (0.00%)<br>0    | 1 / 21 (4.76%)<br>1  |  |

|   |                |                |  |
|---|----------------|----------------|--|
| 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.<br>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.<br>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.<br>reports will be submitted for pregnancies. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported