



Clinical trial results:

A Phase IIIB, observer-blind, randomized, parallel groups, extension study to evaluate the immunogenicity and safety following a single intramuscular dose of FLUAD or Agrippal S1 influenza vaccines in healthy children previously vaccinated in the V70P5 study.

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2010-021644-18 |
| Trial protocol | FI |
| Global end of trial date | 22 December 2011 |

Results information

| | |
|--------------------------------|---|
| Result version number | v2 (current) |
| This version publication date | 29 July 2016 |
| First version publication date | 15 May 2015 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Required for the re-QC project because of the EudraCT system glitch and possible updates to results may be required. Moreover, a change in system user for this study is necessary. |

Trial information

Trial identification

| | |
|-----------------------|---------|
| Sponsor protocol code | V70P5E1 |
|-----------------------|---------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01210898 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Novartis Vaccines and Diagnostics SRL |
| Sponsor organisation address | Via Fiorentina 1, Siena, Italy, 53100 |
| Public contact | Anh Phung, Novartis Vaccines and Diagnostics SRL, RegistryContactVaccinesUS@novartis.com |
| Scientific contact | Anh Phung, Novartis Vaccines and Diagnostics SRL, RegistryContactVaccinesUS@novartis.com |

Notes:

Paediatric regulatory details

| | |
|--|-----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 21 August 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 10 January 2011 |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 December 2011 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

1. To evaluate the immunogenicity of children previously primed with FLUAD® who receive a single IM injection of full dose FLUAD during the extension study.
2. To evaluate the immunogenicity of children previously primed with FLUAD® who receive a single IM injection of half dose FLUAD during the extension study.
3. To evaluate the immunogenicity of children previously primed with FLUAD® who receive a single IM injection of an unadjuvanted influenza vaccine during the extension study.

Protection of trial subjects:

1. Study vaccines were not administered to individuals with known hypersensitivity to any component of the vaccines. An oral temperature $\geq 38.0^{\circ}\text{C}$ ($\geq 100.4^{\circ}\text{F}$) or serious active infection was a reason for delaying vaccination. Standard immunization practices were observed and care was taken to administer the injection intramuscularly. As with all injectable vaccines, appropriate medical treatment and supervision was readily available in case of rare anaphylactic reactions following administration of the study vaccine. Epinephrine 1:1000 and diphenhydramine was available in case of any anaphylactic reactions. Care was taken to ensure that the vaccine is not injected into a blood vessel.
2. This clinical study was designed, implemented and reported in accordance with the International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice, with applicable local regulations (including European Directive 2001/20/EC, US Code of Federal Regulations Title 21, and Japanese Ministry of Health, Labor, and Welfare), and with the ethical principles laid down in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 30 September 2010 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 12 Months |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Finland: 197 |
| Worldwide total number of subjects | 197 |
| EEA total number of subjects | 197 |

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) | 1 |
| Children (2-11 years) | 196 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The number of children to be enrolled during this extension study was up to 1970 children who received two doses of at least one of the vaccines in the V70P5 study, but only 197 subjects were enrolled.

Pre-assignment

Screening details:

All subjects enrolled were included in the trial.

Period 1

| | |
|------------------------------|---------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Subject, Assessor |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|----------------|
| Arm title | MF59-eTIV_Full |
|------------------|----------------|

Arm description:

Subjects who received full dose of MF59-eTIV

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | MF59-eTIV |
| Investigational medicinal product code | |
| Other name | FLUAD |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Each dose of 0.5 mL

| | |
|------------------|----------------|
| Arm title | MF59-eTIV_Half |
|------------------|----------------|

Arm description:

Subjects who received half dose of MF59-eTIV

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | MF59-eTIV |
| Investigational medicinal product code | |
| Other name | FLUAD |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Each dose of 0.25 mL

| | |
|------------------|-------------|
| Arm title | eTIV_a Full |
|------------------|-------------|

Arm description:

Subjects who received full dose of eTIV_a

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | eTIV_a |
| Investigational medicinal product code | |
| Other name | Agrippal S1 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Each dose of 0.5 mL

| | |
|------------------|--------------|
| Arm title | eTIV_a _Half |
|------------------|--------------|

Arm description:

Subjects who received half dose of eTIV_a

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | eTIV_a |
| Investigational medicinal product code | |
| Other name | eTIV_a |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intrasternal use |

Dosage and administration details:

Each dose of 0.25 mL

| Number of subjects in period 1 | MF59-eTIV_Full | MF59-eTIV_Half | eTIV_a Full |
|---------------------------------------|----------------|----------------|-------------|
| Started | 60 | 75 | 51 |
| Completed | 59 | 71 | 47 |
| Not completed | 1 | 4 | 4 |
| Consent withdrawn by subject | - | 2 | 2 |
| Lost to follow-up | 1 | 2 | 2 |

| Number of subjects in period 1 | eTIV_a _Half |
|---------------------------------------|--------------|
| Started | 11 |
| Completed | 11 |
| Not completed | 0 |
| Consent withdrawn by subject | - |
| Lost to follow-up | - |

Baseline characteristics

Reporting groups

| | |
|--|----------------|
| Reporting group title | MF59-eTIV_Full |
| Reporting group description: | |
| Subjects who received full dose of MF59-eTIV | |
| Reporting group title | MF59-eTIV_Half |
| Reporting group description: | |
| Subjects who received half dose of MF59-eTIV | |
| Reporting group title | eTIV_a Full |
| Reporting group description: | |
| Subjects who received full dose of eTIV_a | |
| Reporting group title | eTIV_a _Half |
| Reporting group description: | |
| Subjects who received half dose of eTIV_a | |

| Reporting group values | MF59-eTIV_Full | MF59-eTIV_Half | eTIV_a Full |
|--|----------------|----------------|-------------|
| Number of subjects | 60 | 75 | 51 |
| 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 | 1 | 0 |
| Children (2-11 years) | 60 | 74 | 51 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous | | | |
| Units: months | | | |
| arithmetic mean | 68.7 | 60.4 | 68 |
| standard deviation | ± 18 | ± 23.2 | ± 17.1 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 30 | 40 | 35 |
| Male | 30 | 35 | 16 |

| Reporting group values | eTIV_a _Half | Total | |
|--|--------------|-------|--|
| Number of subjects | 11 | 197 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 1 | |

| | | | |
|---------------------------|-------|-----|--|
| Children (2-11 years) | 11 | 196 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous | | | |
| Units: months | | | |
| arithmetic mean | 32.4 | | |
| standard deviation | ± 1.9 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 5 | 110 | |
| Male | 6 | 87 | |

End points

End points reporting groups

| | |
|---|------------------------------------|
| Reporting group title | MF59-eTIV_Full |
| Reporting group description: | |
| Subjects who received full dose of MF59-eTIV | |
| Reporting group title | MF59-eTIV_Half |
| Reporting group description: | |
| Subjects who received half dose of MF59-eTIV | |
| Reporting group title | eTIV_a Full |
| Reporting group description: | |
| Subjects who received full dose of eTIV_a | |
| Reporting group title | eTIV_a_Half |
| Reporting group description: | |
| Subjects who received half dose of eTIV_a | |
| Subject analysis set title | All Enrolled set |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| All subjects who have signed an informed consent, undergone screening procedure(s) and were randomized. | |
| Subject analysis set title | MF59-eTIV_Half_F_(6-<36 months) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Subjects aged 6-<36 months who received half dose of MF59-eTIV, previously primed with MF59-eTIV in the parent study. | |
| Subject analysis set title | eTIV_a_Half_F_(6-<36 months) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Subjects aged 6-<36 months who received half dose of eTIV_a, previously primed with MF59-eTIV in the parent study. | |
| Subject analysis set title | MF59-eTIV_Half_I_(6-<36 months) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Subjects aged 6 - <36 months who received half dose of MF59-eTIV, previously primed with Influsplit SSW in the parent study. | |
| Subject analysis set title | eTIV_a_Half_I_(6-<36 months) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Subjects aged 6 - <36 months who received half dose of eTIV_a, previously primed with Influsplit SSW in the parent study. | |
| Subject analysis set title | MF59-eTIV_Half_M/E_(6-<36 months) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Subjects aged 6 - <36 months who received half dose of MF59-eTIV, previously primed with Menjugate/Encepur in the parent study. | |
| Subject analysis set title | MF59-eTIV_Full_F_(36 -< 96 months) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Subjects aged 36 - <96 months who received full dose of MF59-eTIV, previously primed with MF59-eTIV in the parent study. | |
| Subject analysis set title | MF59-eTIV_Half_F_(36 -< 96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 36 – <96 months who received half dose of MF59-eTIV, previously primed with MF59-eTIV in the parent study.

| | |
|----------------------------|---------------------------------|
| Subject analysis set title | eTIV_a_Full_F_(36 -< 96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 36 – <96 months who received full dose of eTIV_a, previously primed with MF59-eTIV in the parent study.

| | |
|----------------------------|------------------------------------|
| Subject analysis set title | MF59-eTIV_Full_I_(36 -< 96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 36 – <96 months who received full dose of MF59-eTIV, previously primed with Influsplit SSW in the parent study.

| | |
|----------------------------|------------------------------------|
| Subject analysis set title | MF59-eTIV_Half_I_(36 -< 96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 36 – <96 months who received half dose of MF59-eTIV, previously primed with Influsplit SSW in the parent study.

| | |
|----------------------------|---------------------------------|
| Subject analysis set title | eTIV_a_Full_I_(36 -< 96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 36 – <96 months who received full dose of eTIV_a, previously primed with Influsplit SSW in the parent study.

| | |
|----------------------------|--------------------------------------|
| Subject analysis set title | MF59-eTIV_Full_M/E_(36 -< 96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 36 – <96 months who received full dose of MF59-eTIV, previously primed with Menjugate/Encepur in the parent study.

| | |
|----------------------------|--------------------------------------|
| Subject analysis set title | MF59-eTIV_Half_M/E_(36 -< 96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 36 – <96 months who received half dose of MF59-eTIV, previously primed with Menjugate/Encepur in the parent study.

| | |
|----------------------------|-----------------|
| Subject analysis set title | Safety Set |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

All subjects in the Exposed population who provided post vaccination and post-baseline safety data.

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | MF59-eTIV_F (6 – <96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 6 – <96 months who received single dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|----------------------------|---------------------------|
| Subject analysis set title | eTIV_a_F (6 – <96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 6 – <96 months who received single dose of eTIV_a, previously primed with MF59-eTIV.

| | |
|----------------------------|------------------------------|
| Subject analysis set title | MF59-eTIV_I (6 – <96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 6 – <96 months who received single dose of MF59-eTIV, previously primed with Influsplit SSW

| | |
|----------------------------|---------------------------|
| Subject analysis set title | eTIV_a_I (6 – <96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 6 – <96 months who received single dose of eTIV_a, previously primed with Influsplit SSW

| | |
|----------------------------|---------------------------------|
| Subject analysis set title | MF59-eTIV_ M/E (6 – <96 months) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects aged 6 – <96 months who received single dose of MF59-eTIV, previously primed with Menjugate/Encepur

| | |
|----------------------------|---------------------------------|
| Subject analysis set title | MF59-eTIV_Full_F (6-<36 months) |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Subjects aged 6 – <36 months who received full dose of MF59-eTIV, previously primed with MF59-eTIV in the parent study.

Primary: The geometric mean ratio (GMRs) determined by HI assay at day 22 using CHMP criteria against homologous strains in subjects who received full dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|-----------------|---|
| End point title | The geometric mean ratio (GMRs) determined by HI assay at day 22 using CHMP criteria against homologous strains in subjects who received full dose of MF59-eTIV, previously primed with MF59-eTIV. ^[1] |
|-----------------|---|

End point description:

The immune response was measured as the geometric mean ratio (GMRs) directed against HI homologous strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects who received full dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Day 22

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: No inferential statistical analysis was done.

| End point values | MF59-eTIV_Full_F_(36 -< 96 months) | | | |
|--|------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 22 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/H1N1 | 25 (16 to 38) | | | |
| A/H3N2 | 12 (6.39 to 24) | | | |
| Strain B | 18 (10 to 30) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: The seroconversion (SC) or significant increase (SI) and seroprotection (SP) determined by HI assay at day 22 using CHMP criteria in subjects against

homologous strains who received full dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|-----------------|--|
| End point title | The seroconversion (SC) or significant increase (SI) and seroprotection (SP) determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received full dose of MF59-eTIV, previously primed with MF59-eTIV. ^[2] |
|-----------------|--|

End point description:

The immune response was measured as the SC or SI (Seroconversion rates defined as: HI \geq 40 for subjects negative at baseline [< 10]; or a minimum 4-fold increase in HI titer for subjects positive at baseline [HI ≥ 10]) and SP (Seroprotection defined as the percentage of subjects with HI titer ≥ 40) directed against HI homologous strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects who received full dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Day 22

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: No inferential statistical analysis was done.

| | | | | |
|----------------------------------|-------------------------------------|--|--|--|
| End point values | MF59-eTIV_Full_F_(36 - < 96 months) | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 22 | | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 100 (85 to 100) | | | |
| A/H3N2 (SC or SI) | 77 (55 to 92) | | | |
| Strain B (SC or SI) | 86 (65 to 97) | | | |
| A/H1N1 (HI titer ≥ 40) | 100 (85 to 100) | | | |
| A/H3N2 (HI titer ≥ 40) | 100 (85 to 100) | | | |
| Strain B (HI titer ≥ 40) | 100 (85 to 100) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: The GMRs determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received half dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|-----------------|--|
| End point title | The GMRs determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received half dose of MF59-eTIV, previously primed with MF59-eTIV. ^[3] |
|-----------------|--|

End point description:

The immune response was measured as the geometric mean ratio (GMRs) directed against HI homologous strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects who received half dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| Day 22 | |
| 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: No inferential statistical analysis was done. | |

| End point values | MF59-eTIV_Half_F_(6-<36 months) | MF59-eTIV_Half_F_(36 -< 96 months) | | |
|--|---------------------------------|------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 8 | 18 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/H1N1 | 9.93 (3.53 to 28) | 18 (12 to 29) | | |
| A/H3N2 | 25 (12 to 49) | 13 (6.32 to 28) | | |
| Strain B | 11 (6.1 to 21) | 14 (7.54 to 25) | | |

Statistical analyses

No statistical analyses for this end point

Primary: The SC or SI and SP determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received half dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|-----------------|---|
| End point title | The SC or SI and SP determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received half dose of MF59-eTIV, previously primed with MF59-eTIV. ^[4] |
|-----------------|---|

End point description:

The immune response was measured as the Seroconversion or Significant Increase (Seroconversion rates defined as: HI \geq 40 for subjects negative at baseline [$<$ 10]) and Seroprotection (Seroprotection defined as the percentage of subjects with HI titer \geq 40) directed against HI homologous strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects who received half dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| Day 22 | |
| 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: No inferential statistical analysis was done. | |

| End point values | MF59-eTIV_Half_F_(6-<36 months) | MF59-eTIV_Half_F_(36-<96 months) | | |
|----------------------------------|---------------------------------|----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 8 | 18 | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 75 (35 to 97) | 94 (73 to 100) | | |
| A/H3N2 (SC or SI) | 100 (63 to 100) | 72 (47 to 90) | | |
| Strain B (SC or SI) | 88 (47 to 100) | 78 (52 to 94) | | |
| A/H1N1 (HI titer ≥ 40) | 75 (37 to 97) | 100 (81 to 100) | | |
| A/H3N2 (HI titer ≥ 40) | 100 (63 to 100) | 100 (81 to 100) | | |
| Strain B (HI titer ≥ 40) | 88 (47 to 100) | 83 (59 to 96) | | |

Statistical analyses

No statistical analyses for this end point

Primary: The GMRs determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received single dose of eTIV_a, previously primed with MF59-eTIV.

| | |
|-----------------|---|
| End point title | The GMRs determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received single dose of eTIV_a, previously primed with MF59-eTIV. ^[5] |
|-----------------|---|

End point description:

The immune response was measured as the geometric mean ratio (GMRs) directed against HI homologous strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects who received single dose of eTIV_a, previously primed with MF59-eTIV.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Day 22

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: No inferential statistical analysis was done.

| End point values | eTIV_a_Half_F_(6-<36 months) | eTIV_a_Full_F_(36-<96 months) | | |
|--|------------------------------|-------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 7 | 23 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/H1N1 | 24 (7.87 to 72) | 8.89 (5.92 to 13) | | |
| A/H3N2 | 22 (10 to 45) | 5.41 (2.82 to 10) | | |
| Strain B | 5.94 (3.07 to 12) | 12 (7.18 to 21) | | |

Statistical analyses

No statistical analyses for this end point

Primary: The SC or SI and SP determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received single dose of eTIV_a, previously primed with MF59-eTIV.

| | |
|-----------------|--|
| End point title | The SC or SI and SP determined by HI assay at day 22 using CHMP criteria in subjects against homologous strains who received single dose of eTIV_a, previously primed with MF59-eTIV. ^[6] |
|-----------------|--|

End point description:

The immune response was measured as the Seroconversion or Significant Increase (Seroconversion rates defined as: HI \geq 40 for subjects negative at baseline [$<$ 10]; or a minimum 4-fold increase in HI titer for subjects positive at baseline [HI \geq 10]) and Seroprotection (Seroprotection defined as the percentage of subjects with HI titer \geq 40) directed against HI homologous strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects who received a single dose of eTIV_a, previously primed with MF59-eTIV.

| | |
|----------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| Day 22 | |

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: No inferential statistical analysis was done.

| End point values | eTIV_a_Half_F_(6-<36 months) | eTIV_a_Full_F_(36-<96 months) | | |
|----------------------------------|------------------------------|-------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 7 | 23 | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 86 (42 to 100) | 87 (66 to 97) | | |
| A/H3N2 (SC or SI) | 100 (59 to 100) | 52 (31 to 73) | | |
| Strain B (SC or SI) | 88 (59 to 100) | 74 (52 to 90) | | |
| A/H1N1 (HI titer \geq 40) | 100 (59 to 100) | 96 (78 to 100) | | |
| A/H3N2 (HI titer \geq 40) | 100 (59 to 100) | 100 (85 to 100) | | |
| Strain B (HI titer \geq 40) | 100 (59 to 100) | 83 (61 to 95) | | |

Statistical analyses

Secondary: Percentages of subjects with SC/SI and SP using CBER criteria after receiving full dose of MF59-eTIV, against homologous strains in subjects previously primed with MF59-eTIV.

| | |
|-----------------|--|
| End point title | Percentages of subjects with SC/SI and SP using CBER criteria after receiving full dose of MF59-eTIV, against homologous strains in subjects previously primed with MF59-eTIV. |
|-----------------|--|

End point description:

The immune response was measured as percentage of subjects with Seroconversion/significant increase and Seroprotection using CBER criteria (CBER criterion for seroconversion = the lower limit of the two-sided 95% CI for the percentage of subjects achieving seroconversion for HI antibody $\geq 40\%$, CBER criterion = the lower limit of the two-sided 95% CI for the percentage of subjects achieving an HI antibody titer ≥ 40 is $\geq 70\%$) at day 22 directed against HI homologous strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects received full dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 22

| End point values | MF59-eTIV_Full_F_(36 -< 96 months) | | | |
|----------------------------------|------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 22 | | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 100 (85 to 100) | | | |
| A/H3N2 (SC or SI) | 77 (55 to 92) | | | |
| Strain B (SC or SI) | 86 (65 to 97) | | | |
| A/H1N1 (HI titer ≥ 40) | 100 (85 to 100) | | | |
| A/H3N2 (HI titer ≥ 40) | 100 (85 to 100) | | | |
| Strain B (HI titer ≥ 40) | 100 (85 to 100) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with SC/SI and SP using CBER criteria after receiving half dose of MF59-eTIV, against homologous strains in subjects previously primed with MF59-eTIV.

| | |
|-----------------|--|
| End point title | Percentages of subjects with SC/SI and SP using CBER criteria after receiving half dose of MF59-eTIV, against homologous strains in subjects previously primed with MF59-eTIV. |
|-----------------|--|

End point description:

The immune response was measured as percentage of subjects with Seroconversion or Significant Increase (Seroconversion rates defined as: HI \geq 40 for subjects negative at baseline [< 10]; or a minimum 4-fold increase in HI titer for subjects positive at baseline [HI ≥ 10]) and Seroprotection (Seroprotection defined as the percentage of subjects with HI titer ≥ 40) using CBER criteria at day 22 directed against HI homologous strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects received half dose of MF59-eTIV, previously primed with MF59-eTIV.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 22 | |

| End point values | MF59-eTIV_Half_F_(6-<36 months) | MF59-eTIV_Half_F_(36-< 96 months) | | |
|----------------------------------|---------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 8 | 18 | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 75 (35 to 97) | 94 (73 to 100) | | |
| A/H3N2 (SC or SI) | 100 (63 to 100) | 72 (47 to 90) | | |
| Strain B (SC or SI) | 88 (47 to 100) | 78 (52 to 94) | | |
| A/H1N1 (HI titer ≥ 40) | 75 (35 to 97) | 100 (81 to 100) | | |
| A/H3N2 (HI titer ≥ 40) | 100 (63 to 100) | 100 (81 to 100) | | |
| Strain B (HI titer ≥ 40) | 88 (47 to 100) | 83 (59 to 96) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with SC/SI and SP using CBER criteria after receiving single dose of eTIV_a, against homologous strains in subjects previously primed with MF59-eTIV.

| | |
|-----------------|---|
| End point title | Percentages of subjects with SC/SI and SP using CBER criteria after receiving single dose of eTIV_a, against homologous strains in subjects previously primed with MF59-eTIV. |
|-----------------|---|

End point description:

The immune response was measured as percentage of subjects with Seroconversion or Significant Increase (Seroconversion rates defined as: HI \geq 40 for subjects negative at baseline [< 10]; or a minimum 4-fold increase in HI titer for subjects positive at baseline [HI ≥ 10]) and Seroprotection (Seroprotection defined as the percentage of subjects with HI titer ≥ 40) using CBER criteria at day 22 directed against HI homologous Strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects' received single dose of eTIV_a, previously primed with MF59-eTIV.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 22 | |

| End point values | eTIV_a_Half_F_(6-<36 months) | eTIV_a_Full_F_(36 -< 96 months) | | |
|----------------------------------|------------------------------|---------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 7 | 23 | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 86 (42 to 100) | 87 (66 to 97) | | |
| A/H3N2 (SC or SI) | 100 (59 to 100) | 52 (31 to 73) | | |
| Strain B (SC or SI) | 100 (59 to 100) | 74 (52 to 90) | | |
| A/H1N1 (HI titer ≥ 40) | 100 (59 to 100) | 96 (78 to 100) | | |
| A/H3N2 (HI titer ≥ 40) | 100 (59 to 100) | 100 (85 to 100) | | |
| Strain B (HI titer ≥ 40) | 100 (59 to 100) | 83 (61 to 95) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The GMTs determined by HI assay and compared at day 22 in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|-----------------|--|
| End point title | The GMTs determined by HI assay and compared at day 22 in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur |
|-----------------|--|

End point description:

The immune response was measured as the geometric mean titers (GMTs) directed against HI homologous Strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 and compared in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 22

| End point values | MF59-eTIV_Half_F_(6-<36 months) | eTIV_a_Half_F_(6-<36 months) | MF59-eTIV_Half_I_(6-<36 months) | eTIV_a_Half_I_(6-<36 months) |
|----------------------------------|---------------------------------|------------------------------|---------------------------------|------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 8 | 7 | 7 | 3 |
| Units: Titers | | | | |
| number (confidence interval 95%) | | | | |

| | | | | |
|----------|--------------------|--------------------|--------------------|--------------------|
| A/H1N1 | 515 (134 to 1986) | 552 (130 to 2334) | 1723 (984 to 3017) | 1016 (432 to 2391) |
| A/H3N2 | 1174 (574 to 2400) | 1159 (540 to 2491) | 305 (118 to 789) | 63 (15 to 272) |
| Strain B | 113 (51 to 253) | 160 (68 to 378) | 10 (5.09 to 20) | 20 (7.13 to 56) |

| End point values | MF59-eTIV_Half_M/E_(6-<36 months) | MF59-eTIV_Full_F_(36-<96 months) | MF59-eTIV_Half_F_(36-<96 months) | eTIV_a_Full_F_(36-<96 months) |
|----------------------------------|-----------------------------------|----------------------------------|----------------------------------|-------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 2 | 22 | 18 | 23 |
| Units: Titers | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 | 1522 (2.06 to 1125772) | 1093 (672 to 1779) | 1776 (1037 to 3042) | 488 (303 to 785) |
| A/H3N2 | 320 (-9999 to 9999) | 2021 (1469 to 2781) | 1993 (1401 to 2836) | 680 (498 to 929) |
| Strain B | 20 (20 to 20) | 150 (96 to 235) | 109 (66 to 178) | 99 (64 to 153) |

| End point values | MF59-eTIV_Full_I_(36-<96 months) | MF59-eTIV_Half_I_(36-<96 months) | eTIV_a_Full_I_(36-<96 months) | MF59-eTIV_Full_M/E_(36-<96 months) |
|----------------------------------|----------------------------------|----------------------------------|-------------------------------|------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 22 | 28 | 28 | 14 |
| Units: Titers | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 | 1498 (962 to 2333) | 1249 (843 to 1849) | 707 (477 to 1046) | 2377 (1411 to 4005) |
| A/H3N2 | 934 (572 to 1525) | 780 (505 to 1205) | 308 (200 to 476) | 2152 (1252 to 3702) |
| Strain B | 72 (41 to 124) | 45 (28 to 74) | 26 (16 to 43) | 54 (21 to 138) |

| End point values | MF59-eTIV_Half_M/E_(36-<96 months) | | | |
|----------------------------------|------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 11 | | | |
| Units: Titers | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 | 1164 (646 to 2098) | | | |
| A/H3N2 | 1452 (788 to 2676) | | | |
| Strain B | 43 (15 to 123) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The GMRs determined by HI assay and compared at day 22 in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|-----------------|--|
| End point title | The GMRs determined by HI assay and compared at day 22 in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur |
|-----------------|--|

End point description:

The immune response was measured as the geometric mean ratios (GMRs) directed against HI homologous Strains A/California/2009 (A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 and compared in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 22

| End point values | MF59-eTIV_Half_F (6-<36 months) | eTIV_a_Half_F (6-<36 months) | MF59-eTIV_Half_I (6-<36 months) | eTIV_a_Half_I (6-<36 months) |
|--|---------------------------------|------------------------------|---------------------------------|------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 8 | 7 | 7 | 3 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/H1N1 | 9.93 (3.53 to 28) | 24 (7.87 to 72) | 32 (14 to 74) | 32 (8.86 to 116) |
| A/H3N2 | 25 (12 to 49) | 22 (10 to 45) | 20 (8.72 to 48) | 10 (2.73 to 37) |
| Strain B | 11 (6.1 to 21) | 5.94 (3.07 to 12) | 2 (1.02 to 3.93) | 4 (1.43 to 11) |

| End point values | MF59-eTIV_Half_M/E (6-<36 months) | MF59-eTIV_Full_F (36-<96 months) | MF59-eTIV_Half_F (36-<96 months) | eTIV_a_Full_F (36-<96 months) |
|--|-----------------------------------|----------------------------------|----------------------------------|-------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 2 | 22 | 18 | 23 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |

| | | | | |
|----------|----------------------|-----------------|-----------------|-------------------|
| A/H1N1 | 19 (2.11 to 172) | 25 (16 to 38) | 18 (12 to 29) | 8.89 (5.92 to 13) |
| A/H3N2 | 2.83 (-9999 to 9999) | 12 (6.39 to 24) | 13 (6.32 to 28) | 5.41 (2.82 to 10) |
| Strain B | 4 (4 to 4) | 18 (10 to 30) | 14 (7.54 to 25) | 12 (7.18 to 21) |

| End point values | MF59-eTIV_Full_I_(36 -< 96 months) | MF59-eTIV_Half_I_(36 -< 96 months) | eTIV_a_Full_I_(36 -< 96 months) | MF59-eTIV_Full_M/E_(36 -< 96 months) |
|--|------------------------------------|------------------------------------|---------------------------------|--------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 22 | 28 | 28 | 14 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/H1N1 | 32 (17 to 58) | 21 (12 to 36) | 13 (7.32 to 22) | 24 (13 to 45) |
| A/H3N2 | 17 (9.51 to 31) | 15 (9.08 to 26) | 10 (6.11 to 17) | 17 (9.83 to 29) |
| Strain B | 9.51 (6.19 to 15) | 6.9 (4.71 to 10) | 4.2 (2.87 to 6.16) | 9.28 (4.44 to 19) |

| End point values | MF59-eTIV_Half_M/E_(36 -< 96 months) | | | |
|--|--------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 11 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/H1N1 | 35 (17 to 72) | | | |
| A/H3N2 | 12 (6.79 to 23) | | | |
| Strain B | 5.15 (2.24 to 12) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The SC or SI and SP determined by HI assay at day 22 and compared in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|-----------------|---|
| End point title | The SC or SI and SP determined by HI assay at day 22 and compared in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur |
|-----------------|---|

End point description:

The immune response was measured as the Seroconversion or Significant Increase (Seroconversion rates defined as: HI \geq 40 for subjects negative at baseline [$<$ 10]; or a minimum 4-fold increase in HI titer for subjects positive at baseline [HI \geq 10]) and Seroprotection (Seroprotection defined as the percentage of subjects with HI titer \geq 40) directed against HI homologous Strains A/California/2009

(A/H1N1), A/Perth/2009 (A/H3N2) and B/Brisbane/2008 in subjects who received a single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 22 | |

| End point values | MF59-eTIV_Half_F_(6-<36 months) | eTIV_a_Half_F_(6-<36 months) | MF59-eTIV_Half_I_(6-<36 months) | eTIV_a_Half_I_(6-<36 months) |
|----------------------------------|---------------------------------|------------------------------|---------------------------------|------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 8 | 7 | 7 | 3 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 75 (35 to 97) | 86 (42 to 100) | 100 (59 to 100) | 100 (29 to 100) |
| A/H3N2 (SC or SI) | 100 (63 to 100) | 100 (59 to 100) | 100 (59 to 100) | 100 (29 to 100) |
| Strain B (SC or SI) | 88 (47 to 100) | 100 (59 to 100) | 14 (0 to 58) | 33 (1 to 91) |
| A/H1N1(HI titer≥40) | 75 (35 to 97) | 100 (59 to 100) | 100 (59 to 100) | 100 (29 to 100) |
| A/H3N2 (HI titer≥40) | 100 (63 to 100) | 100 (59 to 100) | 100 (59 to 100) | 100 (29 to 100) |
| Strain B (HI titer ≥40) | 88 (47 to 100) | 100 (59 to 100) | 14 (0 to 58) | 33 (1 to 91) |

| End point values | MF59-eTIV_Half_M/E_(6-<36 months) | MF59-eTIV_Full_F_(36-<96 months) | MF59-eTIV_Half_F_(36-<96 months) | eTIV_a_Full_F_(36-<96 months) |
|----------------------------------|-----------------------------------|----------------------------------|----------------------------------|-------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 2 | 22 | 18 | 23 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 100 (16 to 100) | 100 (85 to 100) | 94 (73 to 100) | 87 (66 to 97) |
| A/H3N2 (SC or SI) | 50 (1 to 99) | 77 (55 to 92) | 72 (47 to 90) | 52 (31 to 73) |
| Strain B (SC or SI) | 0 (0 to 84) | 86 (65 to 97) | 78 (52 to 94) | 74 (52 to 90) |
| A/H1N1(HI titer≥40) | 100 (16 to 100) | 100 (85 to 100) | 100 (81 to 100) | 96 (78 to 100) |
| A/H3N2 (HI titer≥40) | 100 (16 to 100) | 100 (85 to 100) | 100 (81 to 100) | 100 (85 to 100) |
| Strain B (HI titer ≥40) | 0 (0 to 84) | 100 (85 to 100) | 83 (59 to 96) | 83 (61 to 95) |

| End point values | MF59-eTIV_Full_I_(36-<96 months) | MF59-eTIV_Half_I_(36-<96 months) | eTIV_a_Full_I_(36-<96 months) | MF59-eTIV_Full_M/E_(36-<96 months) |
|------------------|----------------------------------|----------------------------------|-------------------------------|------------------------------------|
|------------------|----------------------------------|----------------------------------|-------------------------------|------------------------------------|

| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
|----------------------------------|----------------------|----------------------|----------------------|----------------------|
| Number of subjects analysed | 22 | 28 | 28 | 14 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 100 (85 to 100) | 96 (82 to 100) | 86 (67 to 96) | 100 (77 to 100) |
| A/H3N2 (SC or SI) | 86 (65 to 97) | 82 (63 to 94) | 82 (63 to 94) | 100 (77 to 100) |
| Strain B (SC or SI) | 59 (36 to 79) | 57 (37 to 76) | 39 (22 to 59) | 64 (35 to 87) |
| A/H1N1(HI titer≥40) | 100 (85 to 100) | 100 (88 to 100) | 100 (88 to 100) | 100 (77 to 100) |
| A/H3N2 (HI titer≥40) | 100 (85 to 100) | 100 (88 to 100) | 100 (88 to 100) | 100 (77 to 100) |
| Strain B (HI titer ≥40) | 64 (41 to 83) | 57 (37 to 76) | 43 (24 to 63) | 64 (35 to 87) |

| End point values | MF59-eTIV_Half_M/E_(36 -< 96 months) | | | |
|----------------------------------|--------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| A/H1N1 (SC or SI) | 100 (72 to 100) | | | |
| A/H3N2 (SC or SI) | 100 (72 to 100) | | | |
| Strain B (SC or SI) | 27 (6 to 61) | | | |
| A/H1N1(HI titer≥40) | 100 (72 to 100) | | | |
| A/H3N2 (HI titer≥40) | 100 (72 to 100) | | | |
| Strain B (HI titer ≥40) | 36 (11 to 69) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The GMTs determined by HI assay and compared at day 22 in subjects who received single dose of MF59-eTIV/eTIV_a against heterologous strains previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|-----------------|--|
| End point title | The GMTs determined by HI assay and compared at day 22 in subjects who received single dose of MF59-eTIV/eTIV_a against heterologous strains previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur |
|-----------------|--|

End point description:

The immune response was measured as the geometric mean titers (GMTs) directed against HI heterologous Strains A/Brisbane/59/2007 (A/H1N1)/ A/Brisbane/10/2007 (A/H3N2)/ B/Malaysia/2506/2004/ B/Florida/2006 and compared in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

| End point values | MF59-eTIV_F (6 – <96 months) | eTIV_a _ F (6 – <96 months) | MF59-eTIV_ I (6 – <96 months) | eTIV_a _ I (6 – <96 months) |
|---|-------------------------------------|--------------------------------|-------------------------------------|--------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 48 | 30 | 57 | 31 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/Brisbane/59/2007(A/H1N1)/ | 199 (152 to 259) | 214 (152 to 299) | 58 (37 to 90) | 59 (32 to 108) |
| A/Brisbane/10/2007(A/H3N2)/ | 2017 (1607 to 2532) | 895 (671 to 1193) | 701 (506 to 971) | 239 (154 to 372) |
| B/Malaysia/2506/2004 | 52 (40 to 67) | 40 (29 to 56) | 21 (16 to 28) | 13 (8.8 to 19) |
| B/Florida/2006 | 271 (205 to 359) | 178 (125 to 253) | 64 (49 to 84) | 54 (38 to 78) |

| End point values | MF59-eTIV_ M/E (6 – <96 months) | | | |
|---|---------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 27 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/Brisbane/59/2007(A/H1N1)/ | 40 (22 to 72) | | | |
| A/Brisbane/10/2007(A/H3N2)/ | 1170 (609 to 2247) | | | |
| B/Malaysia/2506/2004 | 17 (9.78 to 29) | | | |
| B/Florida/2006 | 25 (16 to 38) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The GMRs determined by HI assay and compared at day 22 in subjects who received single dose of MF59-eTIV/eTIV_a, against heterologous strains previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|-----------------|---|
| End point title | The GMRs determined by HI assay and compared at day 22 in subjects who received single dose of MF59-eTIV/eTIV_a, against heterologous strains previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur |
|-----------------|---|

End point description:

The immune response was measured as the geometric mean ratios (GMRs) directed against HI heterologous Strains A/Brisbane/59/2007 (A/H1N1)/ A/Brisbane/10/2007 (A/H3N2)/ B/Malaysia/2506/2004/ B/Florida/2006 and compared in subjects who received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 22 | |

| End point values | MF59-eTIV_F (6 – <96 months) | eTIV_a _ F (6 – <96 months) | MF59-eTIV_ I (6 – <96 months) | eTIV_a _ I (6 – <96 months) |
|---|-------------------------------------|--------------------------------|-------------------------------------|--------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 48 | 30 | 57 | 31 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/Brisbane/59/2007(A/H1N1)/ | 1.94 (1.63 to 2.31) | 1.29 (1.03 to 1.61) | 1.91 (1.63 to 2.23) | 1.48 (1.2 to 1.83) |
| A/Brisbane/10/2007(A/H3N2)/ | 8.98 (6.17 to 13) | 5.16 (3.21 to 8.28) | 11 (7.66 to 14) | 7.32 (4.76 to 11) |
| B/Malaysia/2506/2004 | 7.07 (5.57 to 8.98) | 6.13 (4.54 to 8.3) | 3.44 (2.64 to 4.48) | 2.53 (1.77 to 3.62) |
| B/Florida/2006 | 9.04 (6.01 to 14) | 4.87 (2.9 to 8.17) | 3.9 (3 to 5.08) | 2.7 (1.89 to 3.87) |

| End point values | MF59-eTIV_ M/E (6 – <96 months) | | | |
|---|---------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 27 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/Brisbane/59/2007(A/H1N1)/ | 2.05 (1.57 to 2.68) | | | |
| A/Brisbane/10/2007(A/H3N2)/ | 8.98 (6.24 to 13) | | | |
| B/Malaysia/2506/2004 | 3.02 (1.83 to 4.97) | | | |
| B/Florida/2006 | 3.06 (2.09 to 4.47) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with SC/SI and SP after receiving single dose of MF59-eTIV/eTIV_a, against heterologous strains previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur.

| | |
|-----------------|--|
| End point title | Percentages of subjects with SC/SI and SP after receiving single dose of MF59-eTIV/eTIV_a, against heterologous strains previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur. |
|-----------------|--|

End point description:

The immune response was measured as percentage of subjects with seroconversion/significant increase (Seroconversion rates defined as: HI \geq 40 for subjects negative at baseline [HI $<$ 10]; or a minimum 4-fold increase in HI titer for subjects positive at baseline [HI \geq 10]) and Seroprotection (Seroprotection defined as the percentage of subjects with HI titer \geq 40) at day 22 directed against HI heterologous Strains A/Brisbane/59/2007 (A/H1N1)/ A/Brisbane/10/2007 (A/H3N2)/ B/Malaysia/2506/2004/ B/Florida/2006 in subjects' received single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

End point type Secondary

End point timeframe:

Day 22

| End point values | MF59-eTIV_F (6 – <96 months) | eTIV_a _ F (6 – <96 months) | MF59-eTIV _ I (6 – <96 months) | eTIV_a _ I (6 – <96 months) |
|---|-------------------------------------|--------------------------------|--------------------------------------|--------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 48 | 30 | 57 | 31 |
| Units: Percentages of subjects | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/Brisbane/59/2007(A/H1N1)/ (SC or SI) | 25 (14 to 40) | 3 (0.084 to 17) | 16 (7 to 28) | 10 (2 to 26) |
| A/Brisbane/10/2007(A/H3N2)/ (SC or SI) | 71 (56 to 83) | 57 (37 to 75) | 82 (70 to 91) | 74 (55 to 88) |
| B/Malaysia/2506/2004 (SC or SI) | 77 (63 to 88) | 63 (44 to 80) | 37 (24 to 51) | 13 (4 to 30) |
| B/Florida/2006 (SC or SI) | 73 (58 to 85) | 47 (28 to 66) | 53 (39 to 66) | 42 (25 to 61) |
| A/Brisbane/59/2007(A/H1N1)/ (HI titer \geq 40) | 100 (93 to 100) | 100 (88 to 100) | 63 (49 to 76) | 61 (42 to 78) |
| A/Brisbane/10/2007(A/H3N2)/ (HI titer \geq 40) | 100 (93 to 100) | 100 (88 to 100) | 100 (94 to 100) | 94 (79 to 99) |
| B/Malaysia/2506/2004(HI titer \geq 40) | 79 (65 to 90) | 67 (47 to 83) | 39 (26 to 52) | 13 (4 to 30) |
| B/Florida/2006(HI titer \geq 40) | 100 (93 to 100) | 100 (88 to 100) | 81 (68 to 90) | 74 (55 to 88) |

| End point values | MF59-eTIV_ M/E (6 – <96 months) | | | |
|---|---------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 27 | | | |
| Units: Percentages of subjects | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/Brisbane/59/2007(A/H1N1)/ (SC or SI) | 11 (2 to 29) | | | |
| A/Brisbane/10/2007(A/H3N2)/ (SC or SI) | 93 (76 to 99) | | | |
| B/Malaysia/2506/2004 (SC or SI) | 19 (6 to 38) | | | |
| B/Florida/2006 (SC or SI) | 30 (14 to 50) | | | |
| A/Brisbane/59/2007(A/H1N1)/ (HI titer \geq 40) | 48 (29 to 68) | | | |
| A/Brisbane/10/2007(A/H3N2)/ (HI titer \geq 40) | 96 (81 to 100) | | | |
| B/Malaysia/2506/2004(HI titer \geq 40) | 19 (6 to 38) | | | |

| | | | | |
|-----------------------------|---------------|--|--|--|
| B/Florida/2006(HI titer≥40) | 37 (19 to 58) | | | |
|-----------------------------|---------------|--|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Number of children reporting solicited local and systemic adverse events after receiving single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur

| | |
|-----------------|---|
| End point title | Number of children reporting solicited local and systemic adverse events after receiving single dose of MF59-eTIV/eTIV_a, previously primed with MF59-eTIV/ Influsplit SSW/ Menjugate/Encepur |
|-----------------|---|

End point description:

The safety and tolerability of the single dose of MF59-eTIV/eTIV_a vaccine in children (6-<96 months age) is reported as number of subjects with solicited local and systemic adverse events.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From day 1 to day 7 after vaccination

| End point values | MF59-eTIV_Half_F_(6-<36 months) | eTIV_a_Half_F_(6-<36 months) | MF59-eTIV_Half_I_(6-<36 months) | eTIV_a_Half_I_(6-<36 months) |
|-----------------------------|---------------------------------|------------------------------|---------------------------------|------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 9 | 7 | 7 | 3 |
| Units: Number of subjects | | | | |
| Any | 9 | 7 | 7 | 1 |
| Any local | 9 | 5 | 5 | 1 |
| Injection site Ecchymosis | 0 | 0 | 1 | 0 |
| Injection site Erythema | 3 | 3 | 4 | 0 |
| Injection site Induration | 4 | 2 | 3 | 0 |
| Injection site Swelling | 1 | 3 | 2 | 0 |
| Tenderness | 8 | 4 | 3 | 1 |
| Injection site pain | 0 | 0 | 0 | 0 |
| Any Systemic | 6 | 5 | 5 | 0 |
| Change in eating habits | 3 | 3 | 0 | 0 |
| Sleepiness | 3 | 2 | 2 | 0 |
| Unusual Crying | 5 | 3 | 1 | 0 |
| Irritability | 4 | 3 | 3 | 0 |
| Vomiting | 0 | 0 | 0 | 0 |
| Diarrhea | 2 | 1 | 1 | 0 |
| Chills/Shivering | 1 | 1 | 0 | 0 |
| Malaise | 0 | 0 | 0 | 0 |
| Myalgia | 0 | 0 | 0 | 0 |
| Arthralgia | 0 | 0 | 0 | 0 |
| Headache | 0 | 0 | 0 | 0 |

| | | | | |
|-------------------------|---|---|---|---|
| Fatigue | 0 | 0 | 0 | 0 |
| Fever (≥ 37.3 °C) | 1 | 1 | 0 | 0 |
| Any Other | 5 | 4 | 1 | 0 |
| Temp. (°C) (< 37.2°C) | 0 | 0 | 0 | 0 |
| Analg. Antipyr. Med. | 2 | 2 | 0 | 0 |

| End point values | MF59- eTIV_Half_M/E _(6-<36 months) | MF59- eTIV_Full_F_(3 6-< 96 months) | MF59- eTIV_Half _F_(36-< 96 months) | eTIV_a_Full _F_(36-< 96 months) |
|-----------------------------|--|--|--|---------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 2 | 22 | 18 | 23 |
| Units: Number of subjects | | | | |
| Any | 2 | 21 | 17 | 21 |
| Any local | 2 | 20 | 16 | 21 |
| Injection site Ecchymosis | 0 | 2 | 1 | 1 |
| Injection site Erythema | 1 | 14 | 10 | 13 |
| Injection site Induration | 0 | 8 | 7 | 7 |
| Injection site Swelling | 0 | 10 | 9 | 7 |
| Tenderness | 2 | 0 | 0 | 0 |
| Injection site pain | 0 | 19 | 14 | 17 |
| Any Systemic | 1 | 16 | 13 | 9 |
| Change in eating habits | 0 | 0 | 0 | 0 |
| Sleepiness | 1 | 0 | 0 | 0 |
| Unusual Crying | 0 | 0 | 0 | 0 |
| Irritability | 1 | 0 | 0 | 0 |
| Vomiting | 0 | 0 | 0 | 0 |
| Diarrhea | 0 | 0 | 0 | 0 |
| Chills/Shivering | 0 | 4 | 3 | 2 |
| Malaise | 0 | 8 | 2 | 1 |
| Myalgia | 0 | 10 | 3 | 4 |
| Arthralgia | 0 | 5 | 0 | 3 |
| Headache | 0 | 8 | 2 | 3 |
| Fatigue | 0 | 11 | 9 | 8 |
| Fever (≥ 37.3 °C) | 0 | 6 | 1 | 0 |
| Any Other | 2 | 9 | 6 | 5 |
| Temp. (°C) (< 37.2°C) | 0 | 16 | 17 | 23 |
| Analg. Antipyr. Med. | 0 | 7 | 3 | 3 |

| End point values | MF59- eTIV_Full_I_(3 6-< 96 months) | MF59- eTIV_Half_I_(3 6-< 96 months) | eTIV_a _Full_I_(36-< 96 months) | MF59- eTIV_Full_M/E _(36-< 96 months) |
|-----------------------------|--|--|---------------------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 22 | 28 | 28 | 16 |
| Units: Number of subjects | | | | |
| Any | 20 | 26 | 24 | 15 |
| Any local | 19 | 25 | 21 | 15 |

| | | | | |
|---------------------------|----|----|----|----|
| Injection site Ecchymosis | 1 | 3 | 2 | 3 |
| Injection site Erythema | 9 | 13 | 15 | 8 |
| Injection site Induration | 3 | 4 | 8 | 4 |
| Injection site Swelling | 4 | 2 | 6 | 3 |
| Tenderness | 0 | 0 | 0 | 0 |
| Injection site pain | 19 | 23 | 20 | 15 |
| Any Systemic | 11 | 10 | 15 | 9 |
| Change in eating habits | 0 | 0 | 0 | 0 |
| Sleepiness | 0 | 0 | 0 | 0 |
| Unusual Crying | 0 | 0 | 0 | 0 |
| Irritability | 0 | 0 | 0 | 0 |
| Vomiting | 0 | 0 | 0 | 0 |
| Diarrhea | 0 | 0 | 0 | 0 |
| Chills/Shivering | 3 | 2 | 1 | 3 |
| Malaise | 3 | 3 | 1 | 4 |
| Myalgia | 2 | 6 | 6 | 3 |
| Arthralgia | 2 | 2 | 1 | 1 |
| Headache | 4 | 2 | 4 | 4 |
| Fatigue | 9 | 5 | 7 | 8 |
| Fever (≥ 37.3 °C) | 5 | 1 | 4 | 2 |
| Any Other | 9 | 5 | 7 | 6 |
| Temp. (°C) (< 37.2°C) | 17 | 27 | 24 | 13 |
| Analg. Antipyr. Med. | 6 | 4 | 2 | 2 |

| End point values | MF59- eTIV_Half_M/E _(36 -< 96 months) | MF59- eTIV_Full_F (6- <36 months) | | |
|-----------------------------|---|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 11 | 1 | | |
| Units: Number of subjects | | | | |
| Any | 9 | 1 | | |
| Any local | 6 | 1 | | |
| Injection site Ecchymosis | 2 | 0 | | |
| Injection site Erythema | 5 | 0 | | |
| Injection site Induration | 1 | 1 | | |
| Injection site Swelling | 1 | 0 | | |
| Tenderness | 0 | 1 | | |
| Injection site pain | 6 | 0 | | |
| Any Systemic | 7 | 0 | | |
| Change in eating habits | 0 | 0 | | |
| Sleepiness | 0 | 0 | | |
| Unusual Crying | 0 | 0 | | |
| Irritability | 0 | 0 | | |
| Vomiting | 0 | 0 | | |
| Diarrhea | 0 | 0 | | |
| Chills/Shivering | 2 | 0 | | |
| Malaise | 4 | 0 | | |
| Myalgia | 1 | 0 | | |
| Arthralgia | 1 | 0 | | |

| | | | | |
|-------------------------|----|---|--|--|
| Headache | 2 | 0 | | |
| Fatigue | 3 | 0 | | |
| Fever (≥ 37.3 °C) | 1 | 0 | | |
| Any Other | 3 | 0 | | |
| Temp. (°C) (< 37.2°C) | 10 | 0 | | |
| Analg. Antipyr. Med. | 3 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Throughout the study period

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 17.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------------------------|
| Reporting group title | MF59-eTIV_Half_F_(6-<36 months) |
|-----------------------|---------------------------------|

Reporting group description:

Subjects aged 6-<36 months who received half dose of MF59-eTIV, previously primed with MF59-eTIV in the parent study.

| | |
|-----------------------|------------------------------|
| Reporting group title | eTIV_a_Half_F_(6-<36 months) |
|-----------------------|------------------------------|

Reporting group description:

Subjects aged 6 - <36 months who received half dose of eTIV_a, previously primed with MF59-eTIV in the parent study.

| | |
|-----------------------|------------------------------|
| Reporting group title | eTIV_a_Half_I_(6-<36 months) |
|-----------------------|------------------------------|

Reporting group description:

Subjects aged 6 - <36 months who received half dose of eTIV_a, previously primed with Influsplit SSW in the parent study.

| | |
|-----------------------|---------------------------------|
| Reporting group title | MF59-eTIV_Half_I_(6-<36 months) |
|-----------------------|---------------------------------|

Reporting group description:

Subjects aged 6-<36 months who received half dose of MF59-eTIV, previously primed with Influsplit SSW in the parent study.

| | |
|-----------------------|------------------------------------|
| Reporting group title | MF59-eTIV_Full_F_(36 -< 96 months) |
|-----------------------|------------------------------------|

Reporting group description:

Subjects aged 36 - <96 months who received full dose of MF59-eTIV, previously primed with MF59-eTIV in the parent study.

| | |
|-----------------------|-----------------------------------|
| Reporting group title | MF59-eTIV_Half_M/E_(6-<36 months) |
|-----------------------|-----------------------------------|

Reporting group description:

Subjects aged 6 - <36 months who received half dose of MF59-eTIV, previously primed with Menjugate/Encepur in the parent study.

| | |
|-----------------------|------------------------------------|
| Reporting group title | MF59-eTIV_Half_F_(36 -< 96 months) |
|-----------------------|------------------------------------|

Reporting group description:

Subjects aged 36 - <96 months who received half dose of MF59-eTIV, previously primed with MF59-eTIV in the parent study.

| | |
|-----------------------|---------------------------------|
| Reporting group title | eTIV_a_Full_F_(36 -< 96 months) |
|-----------------------|---------------------------------|

Reporting group description:

Subjects aged 36 - <96 months who received full dose of eTIV_a, previously primed with MF59-eTIV in the parent study.

| | |
|-----------------------|------------------------------------|
| Reporting group title | MF59-eTIV_Full_I_(36 -< 96 months) |
|-----------------------|------------------------------------|

Reporting group description:

Subjects aged 36 - <96 months who received full dose of MF59-eTIV, previously primed with Influsplit SSW in the parent study.

| | |
|-----------------------|------------------------------------|
| Reporting group title | MF59-eTIV_Half_I_(36 -< 96 months) |
|-----------------------|------------------------------------|

Reporting group description:

Subjects aged 36 - <96 months who received half dose of MF59-eTIV, previously primed with Influsplit SSW in the parent study.

| | |
|-----------------------|---------------------------------|
| Reporting group title | MF59-eTIV_Full_F_(6-<36 months) |
|-----------------------|---------------------------------|

Reporting group description:

Subjects aged 6-<36 months who received full dose of MF59-eTIV, previously primed with MF59-eTIV in the parent study.

| | |
|--|--------------------------------------|
| Reporting group title | eTIV_a _Full_I_(36 -< 96 months) |
| Reporting group description: Subjects aged 36 – <96 months who received full dose of eTIV_a, previously primed with Influsplit SSW in the parent study. | |
| Reporting group title | MF59-eTIV_Full_M/E_(36 -< 96 months) |
| Reporting group description: Subjects aged 36 – <96 months who received full dose of MF59-eTIV, previously primed with Menjugate/Encepur in the parent study. | |
| Reporting group title | MF59-eTIV_Half_M/E_(36 -< 96 months) |
| Reporting group description: Subjects aged 36 – <96 months who received half dose of MF59-eTIV, previously primed with Menjugate/Encepur in the parent study. | |

| Serious adverse events | MF59-eTIV_Half_F_(6-<36 months) | eTIV_a _Half_F_(6-<36 months) | eTIV_a _Half_I_(6-<36 months) |
|---|---------------------------------|-------------------------------|-------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Snake bite | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (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 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (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 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (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 |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (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 | MF59-eTIV_Half_I_(6-<36 months) | MF59-eTIV_Full_F_(36 -< 96 months) | MF59-eTIV_Half_M/E_(6-<96 months) |
|-------------------------------|---------------------------------|------------------------------------|-----------------------------------|

| | | | |
|---|----------------|----------------|---------------|
| | | | <36 months) |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Snake bite | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (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 |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (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 | MF59-eTIV_Half_F_(36 -< 96 | eTIV_a_Full_F_(36 -< 96 months) | MF59-eTIV_Full_I_(36 -< 96 months) |
|---|----------------------------|---------------------------------|------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Snake bite | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (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 |
| Infections and infestations | | | |

| | | | |
|---|----------------|----------------|----------------|
| Bronchitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (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 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (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 |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | MF59- eTIV_Half_I_(36 -< | MF59- eTIV_Full_F_(6-<36 | eTIV_a_Full_I_(36 -< 96 months) |
|---|-----------------------------|-----------------------------|---------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Snake bite | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (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 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (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 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (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 |
| Pyelonephritis acute | | | |

| | | | |
|---|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (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 | MF59- eTIV_Full_M/E_(36 - < 96 months) | MF59- eTIV_Half_M/E_(36 - < 96 months) | |
|---|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 0 / 11 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Snake bite | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 0 / 11 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | MF59-eTIV_Half_F_(6- <36 months) | eTIV_a_Half_F_(6- <36 months) | eTIV_a_Half_I_(6- <36 months) |
|---|-------------------------------------|----------------------------------|----------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 9 / 9 (100.00%) | 7 / 7 (100.00%) | 2 / 3 (66.67%) |

| | | | |
|--|----------------|----------------|----------------|
| Investigations | | | |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 7 (14.29%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 7 (14.29%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 1 | 1 |
| Surgical and medical procedures | | | |
| Tonsillectomy | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | 2 / 7 (28.57%) | 0 / 3 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| General disorders and administration site conditions | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Chills | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 7 (14.29%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Crying | | | |
| subjects affected / exposed | 5 / 9 (55.56%) | 3 / 7 (42.86%) | 0 / 3 (0.00%) |
| occurrences (all) | 5 | 3 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | 3 / 7 (42.86%) | 0 / 3 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Injection site haemorrhage | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site induration | | | |
| subjects affected / exposed | 4 / 9 (44.44%) | 2 / 7 (28.57%) | 0 / 3 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 8 / 9 (88.89%) | 4 / 7 (57.14%) | 1 / 3 (33.33%) |
| occurrences (all) | 8 | 4 | 1 |
| Injection site pruritus | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site swelling | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 3 / 7 (42.86%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Injection site warmth | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 7 (14.29%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |

| | | | |
|---|---------------------|---------------------|---------------------|
| Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Diarrhoea subjects affected / exposed occurrences (all) | 2 / 9 (22.22%) 2 | 1 / 7 (14.29%) 2 | 0 / 3 (0.00%) 0 |
| Mouth ulceration subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Stomatitis subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 3 (33.33%) 1 |
| Vomiting subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 2 / 9 (22.22%) 2 | 1 / 7 (14.29%) 1 | 0 / 3 (0.00%) 0 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Tonsillar hypertrophy subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Skin and subcutaneous tissue disorders Hyperhidrosis | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 1 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 3 (0.00%) 0 |
| Psychiatric disorders Eating disorder subjects affected / exposed occurrences (all) | 3 / 9 (33.33%) 3 | 3 / 7 (42.86%) 5 | 0 / 3 (0.00%) 0 |
| Insomnia subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Irritability subjects affected / exposed occurrences (all) | 4 / 9 (44.44%) 4 | 3 / 7 (42.86%) 3 | 0 / 3 (0.00%) 0 |
| Restlessness subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Sleep disorder subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Myalgia subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Infections and infestations Bronchitis subjects affected / exposed occurrences (all) | 2 / 9 (22.22%) 2 | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Conjunctivitis subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 0 / 7 (0.00%) 0 | 1 / 3 (33.33%) 1 |
| Ear infection | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 7 (14.29%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | 3 / 7 (42.86%) | 2 / 3 (66.67%) |
| occurrences (all) | 5 | 4 | 3 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 7 (14.29%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pertussis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |

| | | | |
|-----------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 2 / 9 (22.22%) | 1 / 7 (14.29%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 7 (14.29%) | 2 / 3 (66.67%) |
| occurrences (all) | 0 | 1 | 3 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 7 (14.29%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Varicella | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | MF59-eTIV_Half_I_(6-<36 months) | MF59-eTIV_Full_F_(36 -< | MF59-eTIV_Half_M/E_(6-<36 months) |
|---|---------------------------------|-------------------------|-----------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 7 (100.00%) | 21 / 22 (95.45%) | 2 / 2 (100.00%) |
| Investigations | | | |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Injury, poisoning and procedural complications | | | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |

| | | | |
|---|---------------------|------------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Wound subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Surgical and medical procedures Tonsillectomy subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 8 / 22 (36.36%) 11 | 0 / 2 (0.00%) 0 |
| Migraine subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Somnolence subjects affected / exposed occurrences (all) | 2 / 7 (28.57%) 2 | 0 / 22 (0.00%) 0 | 1 / 2 (50.00%) 1 |
| General disorders and administration site conditions Chills subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 4 / 22 (18.18%) 4 | 0 / 2 (0.00%) 0 |
| Crying subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Fatigue subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 11 / 22 (50.00%) 12 | 0 / 2 (0.00%) 0 |
| Injection site erythema subjects affected / exposed occurrences (all) | 4 / 7 (57.14%) 4 | 14 / 22 (63.64%) 14 | 1 / 2 (50.00%) 1 |
| Injection site haemorrhage subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 2 / 22 (9.09%) 2 | 0 / 2 (0.00%) 0 |
| Injection site induration | | | |

| | | | |
|-----------------------------|----------------|------------------|-----------------|
| subjects affected / exposed | 3 / 7 (42.86%) | 8 / 22 (36.36%) | 0 / 2 (0.00%) |
| occurrences (all) | 3 | 9 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 19 / 22 (86.36%) | 2 / 2 (100.00%) |
| occurrences (all) | 4 | 19 | 2 |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 22 (4.55%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injection site swelling | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 10 / 22 (45.45%) | 0 / 2 (0.00%) |
| occurrences (all) | 2 | 11 | 0 |
| Injection site warmth | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 22 (4.55%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 8 / 22 (36.36%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 9 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 6 / 22 (27.27%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 8 | 0 |
| Immune system disorders | | | |
| Allergy to arthropod bite | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 22 (4.55%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 22 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |

| | | | |
|---|---------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 1 / 22 (4.55%) 1 | 0 / 2 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 4 / 22 (18.18%) 4 | 0 / 2 (0.00%) 0 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 1 / 22 (4.55%) 1 | 0 / 2 (0.00%) 0 |
| Tonsillar hypertrophy subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Hyperhidrosis subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 1 / 22 (4.55%) 1 | 0 / 2 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Psychiatric disorders | | | |
| Eating disorder subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Irritability subjects affected / exposed occurrences (all) | 3 / 7 (42.86%) 3 | 0 / 22 (0.00%) 0 | 1 / 2 (50.00%) 1 |
| Restlessness | | | |

| | | | |
|---|----------------|------------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 5 / 22 (22.73%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 10 / 22 (45.45%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 10 | 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 2 / 22 (9.09%) | 1 / 2 (50.00%) |
| occurrences (all) | 2 | 2 | 1 |
| Ear infection | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 22 (4.55%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |

| | | | |
|-----------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 22 (4.55%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 4 / 22 (18.18%) | 1 / 2 (50.00%) |
| occurrences (all) | 7 | 6 | 1 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pertussis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 3 / 22 (13.64%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 2 / 22 (9.09%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Varicella | | | |

| | | | |
|-----------------------------|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 22 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | MF59-eTIV_Half_F_(36 -< 96 | eTIV_a_Full_F_(36 -< 96 months) | MF59-eTIV_Full_I_(36 -< |
|---|----------------------------|---------------------------------|-------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 17 / 18 (94.44%) | 22 / 23 (95.65%) | 21 / 22 (95.45%) |
| Investigations | | | |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Surgical and medical procedures | | | |
| Tonsillectomy | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 3 / 23 (13.04%) | 5 / 22 (22.73%) |
| occurrences (all) | 2 | 3 | 5 |
| Migraine | | | |

| | | | |
|--|------------------|------------------|------------------|
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 3 / 18 (16.67%) | 2 / 23 (8.70%) | 3 / 22 (13.64%) |
| occurrences (all) | 3 | 2 | 3 |
| Crying | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 9 / 18 (50.00%) | 8 / 23 (34.78%) | 9 / 22 (40.91%) |
| occurrences (all) | 11 | 10 | 10 |
| Injection site erythema | | | |
| subjects affected / exposed | 10 / 18 (55.56%) | 13 / 23 (56.52%) | 9 / 22 (40.91%) |
| occurrences (all) | 10 | 14 | 10 |
| Injection site haemorrhage | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 1 / 23 (4.35%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 1 | 1 |
| Injection site induration | | | |
| subjects affected / exposed | 7 / 18 (38.89%) | 7 / 23 (30.43%) | 3 / 22 (13.64%) |
| occurrences (all) | 7 | 8 | 4 |
| Injection site pain | | | |
| subjects affected / exposed | 14 / 18 (77.78%) | 17 / 23 (73.91%) | 19 / 22 (86.36%) |
| occurrences (all) | 15 | 17 | 19 |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling | | | |
| subjects affected / exposed | 9 / 18 (50.00%) | 7 / 23 (30.43%) | 4 / 22 (18.18%) |
| occurrences (all) | 9 | 8 | 4 |
| Injection site warmth | | | |

| | | | |
|---|----------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Malaise subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | 1 / 23 (4.35%) 1 | 3 / 22 (13.64%) 3 |
| Pyrexia subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | 0 / 23 (0.00%) 0 | 7 / 22 (31.82%) 9 |
| Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 2 / 23 (8.70%) 2 | 0 / 22 (0.00%) 0 |
| Diarrhoea subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 23 (4.35%) 1 | 0 / 22 (0.00%) 0 |
| Mouth ulceration subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Stomatitis subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 23 (0.00%) 0 | 2 / 22 (9.09%) 2 |
| Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 2 / 23 (8.70%) 2 | 0 / 22 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | 1 / 23 (4.35%) 1 | 2 / 22 (9.09%) 2 |
| Oropharyngeal pain | | | |

| | | | |
|---|----------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 1 / 22 (4.55%) 1 |
| Tonsillar hypertrophy subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Hyperhidrosis subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 23 (4.35%) 1 | 2 / 22 (9.09%) 2 |
| Rash subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Psychiatric disorders | | | |
| Eating disorder subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Irritability subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Restlessness subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Sleep disorder subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 23 (0.00%) 0 | 0 / 22 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 3 / 23 (13.04%) 3 | 2 / 22 (9.09%) 2 |
| Myalgia subjects affected / exposed occurrences (all) | 3 / 18 (16.67%) 3 | 4 / 23 (17.39%) 4 | 2 / 22 (9.09%) 2 |
| Infections and infestations | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Bronchitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 23 (4.35%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 1 | 1 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 3 / 23 (13.04%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 3 | 1 |
| Ear infection | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 23 (4.35%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 1 | 1 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 1 / 23 (4.35%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 1 | 1 |
| Otitis media | | | |
| subjects affected / exposed | 6 / 18 (33.33%) | 4 / 23 (17.39%) | 3 / 22 (13.64%) |
| occurrences (all) | 8 | 8 | 5 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------------|----------------|-----------------|-----------------|
| Pertussis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 1 / 23 (4.35%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 1 | 2 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 3 / 23 (13.04%) | 3 / 22 (13.64%) |
| occurrences (all) | 1 | 5 | 5 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Varicella | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | MF59- eTIV_Half_I_(36 -< | MF59- eTIV_Full_F_(6-<36 | eTIV_a_Full_I_(36 - < 96 months) |
|---|-----------------------------|-----------------------------|-------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 27 / 28 (96.43%) | 1 / 1 (100.00%) | 27 / 28 (96.43%) |
| Investigations | | | |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------------|--------------------|----------------------|
| Foreign body subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Humerus fracture subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Ligament sprain subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Wound subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Surgical and medical procedures Tonsillectomy subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 3 / 28 (10.71%) 5 | 0 / 1 (0.00%) 0 | 5 / 28 (17.86%) 5 |
| Migraine subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Somnolence subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| General disorders and administration site conditions Chills subjects affected / exposed occurrences (all) | 2 / 28 (7.14%) 2 | 0 / 1 (0.00%) 0 | 1 / 28 (3.57%) 1 |
| Crying subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Fatigue subjects affected / exposed occurrences (all) | 5 / 28 (17.86%) 10 | 0 / 1 (0.00%) 0 | 7 / 28 (25.00%) 7 |

| | | | |
|--|------------------------|----------------------|------------------------|
| Injection site erythema subjects affected / exposed occurrences (all) | 13 / 28 (46.43%) 13 | 0 / 1 (0.00%) 0 | 15 / 28 (53.57%) 16 |
| Injection site haemorrhage subjects affected / exposed occurrences (all) | 3 / 28 (10.71%) 4 | 0 / 1 (0.00%) 0 | 2 / 28 (7.14%) 2 |
| Injection site induration subjects affected / exposed occurrences (all) | 4 / 28 (14.29%) 4 | 1 / 1 (100.00%) 1 | 8 / 28 (28.57%) 9 |
| Injection site pain subjects affected / exposed occurrences (all) | 23 / 28 (82.14%) 25 | 1 / 1 (100.00%) 1 | 20 / 28 (71.43%) 21 |
| Injection site pruritus subjects affected / exposed occurrences (all) | 2 / 28 (7.14%) 2 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Injection site swelling subjects affected / exposed occurrences (all) | 2 / 28 (7.14%) 2 | 0 / 1 (0.00%) 0 | 6 / 28 (21.43%) 7 |
| Injection site warmth subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Malaise subjects affected / exposed occurrences (all) | 3 / 28 (10.71%) 3 | 0 / 1 (0.00%) 0 | 1 / 28 (3.57%) 1 |
| Pyrexia subjects affected / exposed occurrences (all) | 3 / 28 (10.71%) 4 | 1 / 1 (100.00%) 1 | 5 / 28 (17.86%) 5 |
| Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) | 1 / 28 (3.57%) 2 | 0 / 1 (0.00%) 0 | 3 / 28 (10.71%) 3 |
| Diarrhoea | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Mouth ulceration subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Stomatitis subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 3 / 28 (10.71%) 3 | 1 / 1 (100.00%) 1 | 4 / 28 (14.29%) 4 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 3 / 28 (10.71%) 5 | 0 / 1 (0.00%) 0 | 2 / 28 (7.14%) 2 |
| Tonsillar hypertrophy subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Hyperhidrosis subjects affected / exposed occurrences (all) | 1 / 28 (3.57%) 1 | 0 / 1 (0.00%) 0 | 1 / 28 (3.57%) 1 |
| Rash subjects affected / exposed occurrences (all) | 1 / 28 (3.57%) 1 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Psychiatric disorders | | | |
| Eating disorder subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 28 (0.00%) 0 |
| Insomnia | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Restlessness | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 1 (0.00%) | 1 / 28 (3.57%) |
| occurrences (all) | 3 | 0 | 1 |
| Myalgia | | | |
| subjects affected / exposed | 6 / 28 (21.43%) | 0 / 1 (0.00%) | 6 / 28 (21.43%) |
| occurrences (all) | 6 | 0 | 8 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 1 / 1 (100.00%) | 2 / 28 (7.14%) |
| occurrences (all) | 1 | 1 | 2 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |

| | | | |
|-----------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 1 (0.00%) | 1 / 28 (3.57%) |
| occurrences (all) | 2 | 0 | 1 |
| Otitis media | | | |
| subjects affected / exposed | 6 / 28 (21.43%) | 0 / 1 (0.00%) | 8 / 28 (28.57%) |
| occurrences (all) | 9 | 0 | 14 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pertussis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 1 / 1 (100.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 1 (0.00%) | 1 / 28 (3.57%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper respiratory tract infection | | | |

| | | | |
|-----------------------------|-----------------|---------------|-----------------|
| subjects affected / exposed | 4 / 28 (14.29%) | 0 / 1 (0.00%) | 6 / 28 (21.43%) |
| occurrences (all) | 4 | 0 | 6 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 1 (0.00%) | 1 / 28 (3.57%) |
| occurrences (all) | 1 | 0 | 1 |
| Varicella | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 1 (0.00%) | 0 / 28 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| Non-serious adverse events | MF59- eTIV_Full_M/E_(36 - < 96 months) | MF59- eTIV_Half_M/E_(36 - < 96 months) | |
|---|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 16 / 16 (100.00%) | 10 / 11 (90.91%) | |
| Investigations | | | |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Foreign body | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 0 / 11 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ligament sprain | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 0 / 11 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Wound | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Surgical and medical procedures | | | |
| Tonsillectomy | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|--|------------------|-----------------|--|
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 4 / 16 (25.00%) | 3 / 11 (27.27%) | |
| occurrences (all) | 4 | 4 | |
| Migraine | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Somnolence | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 3 / 16 (18.75%) | 2 / 11 (18.18%) | |
| occurrences (all) | 4 | 2 | |
| Crying | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Fatigue | | | |
| subjects affected / exposed | 8 / 16 (50.00%) | 3 / 11 (27.27%) | |
| occurrences (all) | 12 | 4 | |
| Injection site erythema | | | |
| subjects affected / exposed | 8 / 16 (50.00%) | 5 / 11 (45.45%) | |
| occurrences (all) | 11 | 5 | |
| Injection site haemorrhage | | | |
| subjects affected / exposed | 3 / 16 (18.75%) | 2 / 11 (18.18%) | |
| occurrences (all) | 3 | 2 | |
| Injection site induration | | | |
| subjects affected / exposed | 4 / 16 (25.00%) | 1 / 11 (9.09%) | |
| occurrences (all) | 4 | 1 | |
| Injection site pain | | | |
| subjects affected / exposed | 15 / 16 (93.75%) | 6 / 11 (54.55%) | |
| occurrences (all) | 15 | 6 | |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injection site swelling | | | |

| | | | |
|--|---------------------------------|---------------------------------|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>3 / 16 (18.75%)</p> <p>3</p> | <p>1 / 11 (9.09%)</p> <p>1</p> | |
| <p>Injection site warmth</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 16 (6.25%)</p> <p>1</p> | <p>0 / 11 (0.00%)</p> <p>0</p> | |
| <p>Malaise</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>4 / 16 (25.00%)</p> <p>5</p> | <p>4 / 11 (36.36%)</p> <p>5</p> | |
| <p>Pyrexia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>2 / 16 (12.50%)</p> <p>3</p> | <p>1 / 11 (9.09%)</p> <p>1</p> | |
| <p>Immune system disorders</p> <p>Allergy to arthropod bite</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 16 (0.00%)</p> <p>0</p> | <p>0 / 11 (0.00%)</p> <p>0</p> | |
| <p>Gastrointestinal disorders</p> <p>Abdominal pain upper</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 16 (0.00%)</p> <p>0</p> | <p>1 / 11 (9.09%)</p> <p>1</p> | |
| <p>Diarrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 16 (0.00%)</p> <p>0</p> | <p>0 / 11 (0.00%)</p> <p>0</p> | |
| <p>Mouth ulceration</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 16 (0.00%)</p> <p>0</p> | <p>0 / 11 (0.00%)</p> <p>0</p> | |
| <p>Stomatitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 16 (0.00%)</p> <p>0</p> | <p>0 / 11 (0.00%)</p> <p>0</p> | |
| <p>Vomiting</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 16 (0.00%)</p> <p>0</p> | <p>2 / 11 (18.18%)</p> <p>2</p> | |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>Asthma</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 16 (0.00%)</p> <p>0</p> | <p>0 / 11 (0.00%)</p> <p>0</p> | |
| <p>Cough</p> | | | |

| | | | |
|---|----------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 2 / 16 (12.50%) 2 | 1 / 11 (9.09%) 2 | |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 16 (0.00%) 0 | 0 / 11 (0.00%) 0 | |
| Tonsillar hypertrophy subjects affected / exposed occurrences (all) | 0 / 16 (0.00%) 0 | 0 / 11 (0.00%) 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Hyperhidrosis subjects affected / exposed occurrences (all) | 0 / 16 (0.00%) 0 | 0 / 11 (0.00%) 0 | |
| Rash subjects affected / exposed occurrences (all) | 0 / 16 (0.00%) 0 | 0 / 11 (0.00%) 0 | |
| Psychiatric disorders | | | |
| Eating disorder subjects affected / exposed occurrences (all) | 0 / 16 (0.00%) 0 | 0 / 11 (0.00%) 0 | |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 16 (0.00%) 0 | 0 / 11 (0.00%) 0 | |
| Irritability subjects affected / exposed occurrences (all) | 0 / 16 (0.00%) 0 | 0 / 11 (0.00%) 0 | |
| Restlessness subjects affected / exposed occurrences (all) | 0 / 16 (0.00%) 0 | 0 / 11 (0.00%) 0 | |
| Sleep disorder subjects affected / exposed occurrences (all) | 1 / 16 (6.25%) 1 | 0 / 11 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia subjects affected / exposed occurrences (all) | 1 / 16 (6.25%) 1 | 1 / 11 (9.09%) 1 | |
| Myalgia | | | |

| | | | |
|--|----------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 3 / 16 (18.75%) 3 | 1 / 11 (9.09%) 1 | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 0 / 11 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 0 / 11 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ear infection | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 1 / 11 (9.09%) | |
| occurrences (all) | 1 | 1 | |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 0 / 11 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Impetigo | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Influenza | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 1 / 11 (9.09%) | |
| occurrences (all) | 0 | 1 | |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 1 / 11 (9.09%) | |
| occurrences (all) | 1 | 1 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Otitis media | | | |
| subjects affected / exposed | 2 / 16 (12.50%) | 3 / 11 (27.27%) | |
| occurrences (all) | 2 | 5 | |

| | | | |
|-----------------------------------|-----------------|----------------|--|
| Paronychia | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pertussis | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 1 / 11 (9.09%) | |
| occurrences (all) | 0 | 1 | |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 0 / 11 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rhinitis | | | |
| subjects affected / exposed | 2 / 16 (12.50%) | 0 / 11 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 1 / 11 (9.09%) | |
| occurrences (all) | 0 | 1 | |
| Tonsillitis | | | |
| subjects affected / exposed | 2 / 16 (12.50%) | 0 / 11 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 1 / 11 (9.09%) | |
| occurrences (all) | 1 | 1 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 11 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Varicella | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 1 / 11 (9.09%) | |
| occurrences (all) | 0 | 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported