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	• 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 Florentina 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 ≥38.0°C (≥100.4°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 ≥ 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 ≥ 40 for subjects negative at baseline [< 10]) and Seroprotection (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 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 ≥ 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) 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 ≥ 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: 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 ≥40%, CBER criterion = the lower limit of the two-sided 95% CI for the percentage of subjects achieving an HI antibody titer ≥40 is ≥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 ≥ 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 ≥ 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 ≥ 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) 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 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)/	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 ≥ 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) 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≥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≥40)	100 (93 to 100)	100 (88 to 100)	100 (94 to 100)	94 (79 to 99)
B/Malaysia/2506/2004(HI titer≥40)	79 (65 to 90)	67 (47 to 83)	39 (26 to 52)	13 (4 to 30)
B/Florida/2006(HI titer≥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≥40)	48 (29 to 68)			
A/Brisbane/10/2007(A/H3N2)/ (HI titer≥40)	96 (81 to 100)			
B/Malaysia/2506/2004(HI titer≥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
Arthralagia	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_(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: 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
Arthralagia	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_(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	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
Arthralagia	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		
Arthralagia	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 -<	MF59-eTIV_Half_M/E_(6-

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

subjects affected / exposed	0 / 9 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Eating disorder			
subjects affected / exposed	3 / 9 (33.33%)	3 / 7 (42.86%)	0 / 3 (0.00%)
occurrences (all)	3	5	0
Insomnia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	4 / 9 (44.44%)	3 / 7 (42.86%)	0 / 3 (0.00%)
occurrences (all)	4	3	0
Restlessness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 9 (22.22%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Conjunctivitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	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	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tonsillectomy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 7 (0.00%)	8 / 22 (36.36%)	0 / 2 (0.00%)
occurrences (all)	0	11	0
Migraine			
subjects affected / exposed	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	2 / 7 (28.57%)	0 / 22 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	1
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 7 (0.00%)	4 / 22 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Crying			
subjects affected / exposed	1 / 7 (14.29%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	11 / 22 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	12	0
Injection site erythema			
subjects affected / exposed	4 / 7 (57.14%)	14 / 22 (63.64%)	1 / 2 (50.00%)
occurrences (all)	4	14	1
Injection site haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	2 / 22 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	2	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	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	1 / 22 (4.55%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 7 (14.29%)	4 / 22 (18.18%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 22 (4.55%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 22 (4.55%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Eating disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 22 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	3 / 7 (42.86%)	0 / 22 (0.00%)	1 / 2 (50.00%)
occurrences (all)	3	0	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	0 / 18 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	2 / 18 (11.11%)	1 / 23 (4.35%)	3 / 22 (13.64%)
occurrences (all)	2	1	3
Pyrexia			
subjects affected / exposed	2 / 18 (11.11%)	0 / 23 (0.00%)	7 / 22 (31.82%)
occurrences (all)	2	0	9
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 18 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 18 (0.00%)	2 / 23 (8.70%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	0 / 18 (0.00%)	1 / 23 (4.35%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Mouth ulceration			
subjects affected / exposed	1 / 18 (5.56%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 18 (5.56%)	0 / 23 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 18 (0.00%)	2 / 23 (8.70%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Cough			
subjects affected / exposed	2 / 18 (11.11%)	1 / 23 (4.35%)	2 / 22 (9.09%)
occurrences (all)	2	1	2
Oropharyngeal pain			

subjects affected / exposed	0 / 18 (0.00%)	0 / 23 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Tonsillar hypertrophy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 23 (4.35%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
Rash			
subjects affected / exposed	0 / 18 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Eating disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	1 / 18 (5.56%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	1 / 18 (5.56%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 18 (0.00%)	3 / 23 (13.04%)	2 / 22 (9.09%)
occurrences (all)	0	3	2
Myalgia			
subjects affected / exposed	3 / 18 (16.67%)	4 / 23 (17.39%)	2 / 22 (9.09%)
occurrences (all)	3	4	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	0 / 28 (0.00%)	0 / 1 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 1 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 1 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 28 (0.00%)	0 / 1 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tonsillectomy			
subjects affected / exposed	0 / 28 (0.00%)	0 / 1 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 28 (10.71%)	0 / 1 (0.00%)	5 / 28 (17.86%)
occurrences (all)	5	0	5
Migraine			
subjects affected / exposed	0 / 28 (0.00%)	0 / 1 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 28 (0.00%)	0 / 1 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	2 / 28 (7.14%)	0 / 1 (0.00%)	1 / 28 (3.57%)
occurrences (all)	2	0	1
Crying			
subjects affected / exposed	0 / 28 (0.00%)	0 / 1 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 28 (17.86%)	0 / 1 (0.00%)	7 / 28 (25.00%)
occurrences (all)	10	0	7

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

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

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

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

subjects affected / exposed	3 / 16 (18.75%)	1 / 11 (9.09%)	
occurrences (all)	3	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