



Clinical trial results: Immunogenicity and Safety Study of GSK Biologicals' Quadrivalent Influenza Vaccine (GSK2282512A) When Administered in Children Summary

EudraCT number	2010-021073-36
Trial protocol	ES
Global end of trial date	17 August 2011

Results information

Result version number	v2
This version publication date	19 May 2016
First version publication date	07 March 2015
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Typos were corrected in statistical analyses descriptions

Trial information

Trial identification

Sponsor protocol code	113314
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01198756
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, 1330
Public contact	GlaxoSmithKline Biologicals, GlaxoSmithKline Biologicals, 044 2089904466, mmd10443@gsk.com
Scientific contact	GlaxoSmithKline Biologicals, GlaxoSmithKline Biologicals, 044 2089904466, mmd10443@gsk.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	12 October 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 March 2011
Global end of trial reached?	Yes
Global end of trial date	17 August 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- Evaluar la no inferioridad inmunogénica (según la media geométrica del título [GMT] y la tasa de seroconversión [SCR]), para las cepas virales compartidas de FLU Q-QIV frente a Fluarix-VB y Fluarix-YB en niños de 3 a 17 años, aproximadamente 28 días después de finalizar la pauta de vacunación (aproximadamente día 28 para los sujetos ya vacunados y día 56 para los no vacunados con anterioridad).

Protection of trial subjects:

As with all injectable vaccines, appropriate medical treatment was always readily available in case of anaphylactic reactions following the administration of the vaccine.

For this reason, the vaccinee remained under medical supervision for 30 minutes after vaccination.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 379
Country: Number of subjects enrolled	Mexico: 287
Country: Number of subjects enrolled	Taiwan: 295
Country: Number of subjects enrolled	United States: 1638
Country: Number of subjects enrolled	Spain: 510
Worldwide total number of subjects	3109
EEA total number of subjects	510

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	3109
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:

A total of 3109 subjects were enrolled, out of which solely 3094 subjects were vaccinated who constituted the analysed population in this study.

Pre-assignment

Screening details:

Unprimed Subjects – subjects aged 6 months to 8 years with no H1N1 vaccine or H1N1 infection in the last season, or with no seasonal influenza vaccine in the past or who had received only 1 dose for the first time in the last season – received a 2-dose vaccination course. Primed Subjects – all other subjects – received a 1-dose vaccination course.

Pre-assignment period milestones

Number of subjects started	3109
Number of subjects completed	3094

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Did not receive vaccination: 15
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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	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK2282512A 1 Group

Arm description:

Subjects, 3 to 17 years old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	Quadrivalent seasonal influenza vaccine GSK2282512A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

For subject 3 to 8 years of age, single intramuscular dose for primed subjects, two doses for unprimed subjects. For subjects 9 to 17 years of age, single intramuscular dose.

Arm title	Victoria strain Fluarix Group
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Arm description:

Subjects, 3 to 17 years old, received 1 dose of Fluarix™ VB vaccine containing the Victoria lineage B flu strain at Day 0 or 2 doses of Fluarix™ VB vaccine at Day 0 and Day 28. The Fluarix™ VB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.

Arm type	Active comparator
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Investigational medicinal product name	Fluarix™ VB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

For subject 3 to 8 years of age, single intramuscular dose for primed subjects, two doses for unprimed subjects. For subjects of 9 to 17 years of age, single intramuscular dose.

Arm title	Yamagata strain Fluarix Group
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Arm description:

Subjects, 3 to 17 years old, received 1 dose of Fluarix™ YB vaccine containing the Yamagata lineage B flu strain at Day 0 or 2 doses of Fluarix™ YB vaccine at Day 0 and Day 28. The Fluarix™ YB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.

Arm type	Active comparator
Investigational medicinal product name	Fluarix™ YB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

For subject 3 to 8 years of age, single intramuscular dose for primed subjects, two doses for unprimed subjects. For subjects of 9 to 17 years of age, single intramuscular dose

Arm title	GSK2282512A 2 Group
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Arm description:

Subjects, 6 to 35 months old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm for subjects ≥12 months of age and into the antero-lateral region of the left thigh for infants <12 months of age.

Arm type	Experimental
Investigational medicinal product name	Quadrivalent seasonal influenza vaccine GSK2282512A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single intramuscular dose for primed subjects, two doses for unprimed subjects.

Number of subjects in period 1^[1]	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group
Started	932	929	932
Completed	894	889	902
Not completed	38	40	30
Consent withdrawn by subject	9	-	-
Adverse event, non-fatal	-	-	-
Withdrawal by Subject	-	4	7
Lost to follow-up	29	36	23
Protocol deviation	-	-	-

Number of subjects in period 1^[1]	GSK2282512A 2 Group
Started	301
Completed	275
Not completed	26
Consent withdrawn by subject	-
Adverse event, non-fatal	1
Withdrawal by Subject	5
Lost to follow-up	18
Protocol deviation	2

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Attrition data provided in the Recruitment details and Pre-Assignment period.

Baseline characteristics

Reporting groups

Reporting group title	GSK2282512A 1 Group
Reporting group description:	
Subjects, 3 to 17 years old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Reporting group title	Victoria strain Fluarix Group
Reporting group description:	
Subjects, 3 to 17 years old, received 1 dose of Fluarix™ VB vaccine containing the Victoria lineage B flu strain at Day 0 or 2 doses of Fluarix™ VB vaccine at Day 0 and Day 28. The Fluarix™ VB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Reporting group title	Yamagata strain Fluarix Group
Reporting group description:	
Subjects, 3 to 17 years old, received 1 dose of Fluarix™ YB vaccine containing the Yamagata lineage B flu strain at Day 0 or 2 doses of Fluarix™ YB vaccine at Day 0 and Day 28. The Fluarix™ YB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Reporting group title	GSK2282512A 2 Group
Reporting group description:	
Subjects, 6 to 35 months old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm for subjects ≥12 months of age and into the antero-lateral region of the left thigh for infants <12 months of age.	

Reporting group values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group
Number of subjects	932	929	932
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	932	929	932
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: years			
geometric mean	8.9	8.9	8.9
standard deviation	± 4.21	± 4.23	± 4.17
Gender categorical			
Units: Subjects			
Female	434	455	464
Male	498	474	468

Reporting group values	GSK2282512A 2 Group	Total	
Number of subjects	301	3094	

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)	301	301	
Children (2-11 years)	0	2793	
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: years			
geometric mean	1.2		
standard deviation	± 0.73	-	
Gender categorical Units: Subjects			
Female	143	1496	
Male	158	1598	

End points

End points reporting groups

Reporting group title	GSK2282512A 1 Group
Reporting group description: Subjects, 3 to 17 years old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Reporting group title	Victoria strain Fluarix Group
Reporting group description: Subjects, 3 to 17 years old, received 1 dose of Fluarix™ VB vaccine containing the Victoria lineage B flu strain at Day 0 or 2 doses of Fluarix™ VB vaccine at Day 0 and Day 28. The Fluarix™ VB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Reporting group title	Yamagata strain Fluarix Group
Reporting group description: Subjects, 3 to 17 years old, received 1 dose of Fluarix™ YB vaccine containing the Yamagata lineage B flu strain at Day 0 or 2 doses of Fluarix™ YB vaccine at Day 0 and Day 28. The Fluarix™ YB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Reporting group title	GSK2282512A 2 Group
Reporting group description: Subjects, 6 to 35 months old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm for subjects ≥12 months of age and into the antero-lateral region of the left thigh for infants <12 months of age.	
Subject analysis set title	GSK2282512A 1 (3-8 years) Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects, 3 to 8 years old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Subject analysis set title	GSK2282512A 1 (9-17 years) Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects, 9 to 17 years old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Subject analysis set title	Victoria strain Fluarix (3-8 years) Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects, 3 to 8 years old, received 1 dose of Fluarix™ VB vaccine containing the Victoria lineage B flu strain at Day 0 or 2 doses of Fluarix™ VB vaccine at Day 0 and Day 28. The Fluarix™ VB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Subject analysis set title	Victoria strain Fluarix (9-17 years) Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Victoria strain Fluarix (9-17 years) Group	
Subject analysis set title	Yamagata strain Fluarix (3-8 years) Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects, 3 to 8 years old, received 1 dose of Fluarix™ YB vaccine containing the Yamagata lineage B flu strain at Day 0 or 2 doses of Fluarix™ YB vaccine at Day 0 and Day 28. The Fluarix™ YB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.	
Subject analysis set title	Yamagata strain Fluarix (9-17 years) Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects, 9 to 17 years old, received 1 dose of Fluarix™ YB vaccine containing the Yamagata lineage B flu strain at Day 0 or 2 doses of Fluarix™ YB vaccine at Day 0 and Day 28. The Fluarix™ YB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.

Primary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease
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End point description:

Titers are presented as geometric mean titers (GMTs). The reference cut-off value was the seropositivity cut-off of 1:10. Antibodies assessed were antibodies against the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 (Yamagata) flu strains.

End point type	Primary
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End point timeframe:

At 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	878	871	878	259
Units: titre				
geometric mean (confidence interval 95%)				
H1N1, POST (N=878;871;878;259)	362.7 (335.3 to 392.3)	429.1 (396.5 to 464.3)	420.2 (388.8 to 454)	200.9 (166.6 to 242.2)
H3N2, POST (N=878;871;878;259)	143.7 (134.2 to 153.9)	139.6 (130.5 to 149.3)	151 (141 to 161.6)	61.4 (53.8 to 70)
Victoria, POST (N=878;871;877;259)	250.5 (230.8 to 272)	245.4 (226.9 to 265.4)	68.1 (61.9 to 74.9)	127.3 (109.4 to 148.1)
Yamagata, POST (N=878;871;878;259)	512.5 (477.6 to 549.9)	197 (180.7 to 214.8)	579 (541.2 to 619.3)	192.7 (172.1 to 215.7)

Statistical analyses

Statistical analysis title	Adjusted GMT ratio A/California/7/2009 (H1N1)
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Statistical analysis description:

To assess the non-inferiority in terms of GMTs, the adjusted GMT ratio at post-vaccination with the 2-sided 95% CI for each strain was computed by fitting an Analysis of Covariance (ANCOVA) model including vaccine groups as fixed effect.

Comparison groups	Victoria strain Fluarix Group v GSK2282512A 1 Group v Yamagata strain Fluarix Group
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Number of subjects included in analysis	2627
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	ANCOVA
Parameter estimate	GMT ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.06
upper limit	1.25

Statistical analysis title	Adjusted GMT A/Victoria/210/2009 (H3N2)
Comparison groups	GSK2282512A 1 Group v Victoria strain Fluarix Group v Yamagata strain Fluarix Group
Number of subjects included in analysis	2627
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	ANCOVA
Parameter estimate	Adjusted GMT ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.07

Statistical analysis title	Adjusted GMT ratio B/Brisbane/60/2008 (Victoria)
Comparison groups	GSK2282512A 1 Group v Victoria strain Fluarix Group
Number of subjects included in analysis	1749
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	ANCOVA
Parameter estimate	Adjusted GMT ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.07

Statistical analysis title	Adjusted GMT ratio B/Florida/4/2006 (Yamagata)
Comparison groups	GSK2282512A 1 Group v Yamagata strain Fluarix Group

Number of subjects included in analysis	1756
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	ANCOVA
Parameter estimate	Adjusted GMT ratio
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.16

Statistical analysis title	Difference in SCR A/California/7/2009 (H1N1)
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Statistical analysis description:

A logistic regression model was fitted for the difference in SCR and the 2-sided 95% CI. The following contrasts were performed: for both A strains (California and Victoria), the SCR difference (Victoria strain Fluarix + Yamagata strains Fluarix pooled groups minus GSK2282512A Group)

Comparison groups	GSK2282512A 1 Group v Victoria strain Fluarix Group v Yamagata strain Fluarix Group
Number of subjects included in analysis	2627
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	ANCOVA
Parameter estimate	Difference in SCR (%)
Point estimate	1.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	4.77

Statistical analysis title	Difference in SCR A/Victoria/210/2009 (H3N2)
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Statistical analysis description:

A logistic regression model was fitted for the difference in SCR and the 2-sided 95% CI. The following contrasts were performed: for both A strains (California and Victoria), the SCR difference (Victoris strain Fluarix + Yamagata straing Fluarix pooled groups minus GSK2282512A Group)

Comparison groups	GSK2282512A 1 Group v Victoria strain Fluarix Group v Yamagata strain Fluarix Group
Number of subjects included in analysis	2627
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	ANCOVA
Parameter estimate	Difference in SCR (%)
Point estimate	-1.36

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.05
upper limit	2.41

Statistical analysis title	Difference in SCR B/Brisbane/60/2008 (Victoria)
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Statistical analysis description:

A logistic regression model was fitted for the difference in SCR and the 2-sided 95% CI. The following contrasts were performed for the Victoria B strain, the seroconversion rate (SCR) difference (Victoria strain Fluarix Group minus GSK2282512A Group).

Comparison groups	GSK2282512A 1 Group v Victoria strain Fluarix Group
Number of subjects included in analysis	1749
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	ANCOVA
Parameter estimate	Difference in SCR (%)
Point estimate	-3.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.21
upper limit	1.12

Statistical analysis title	Difference in SCR B/Florida/4/2006 (Yamagata)
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Statistical analysis description:

A logistic regression model was fitted for the difference in SCR and the 2-sided 95% CI. The following contrasts were performed for the Yamagata B strain, the seroconversion rate (SCR) difference (Yamagata strain Fluarix Group minus GSK2282512A Group).

Comparison groups	GSK2282512A 1 Group v Yamagata strain Fluarix Group
Number of subjects included in analysis	1756
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	ANCOVA
Parameter estimate	Difference in SCR (%)
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.89
upper limit	2.3

Primary: Number of subjects seroconverted against 4 strains of influenza disease

End point title	Number of subjects seroconverted against 4 strains of influenza disease ^[1]
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End point description:

A seroconverted subject was defined as a vaccinated subject who had either a pre-vaccination titer < 1:10 and a post-vaccination titer ≥1:40, or a pre-vaccination titer ≥1:10 and at least a four-fold increase in post-vaccination titer. The vaccine strains assessed were the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 (Yamagata) flu strains.

End point type	Primary
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End point timeframe:

At 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	876	870	877	259
Units: Subjects				
H1N1, POST (N=876;870;877;259)	739	755	750	220
H3N2, POST (N=876;870;876;259)	614	590	610	189
Victoria, POST (N=876;870;876;259)	653	622	262	219
Yamagata, POST (N=876;870;877;259)	659	359	644	243

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease
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End point description:

Titers are presented as geometric mean titers (GMTs). The reference cut-off value was the seropositivity cut-off of 1:10. Antibodies assessed were antibodies against the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 (Yamagata) flu strains.

End point type	Secondary
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End point timeframe:

At Day 0 and at 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	878	871	878	259
Units: titre				
geometric mean (confidence interval 95%)				
H1N1, Day 0 (N=876;870;877;259)	29.4 (26.8 to 32.2)	32.2 (29.4 to 35.3)	29.1 (26.6 to 31.8)	16.8 (13.9 to 20.3)
H1N1, POST (N=878;871;878;259)	362.7 (335.3 to 392.3)	429.1 (396.5 to 464.3)	420.2 (388.8 to 454)	200.9 (166.6 to 242.2)
H3N2, Day 0 (N=876;870;876;259)	18.1 (16.7 to 19.7)	19 (17.4 to 20.6)	19.4 (17.8 to 21.1)	5.6 (5.3 to 6)
H3N2, POST (N=878;871;878;259)	143.7 (134.2 to 153.9)	139.6 (130.5 to 149.3)	151 (141 to 161.6)	61.4 (53.8 to 70)
Victoria, Day 0 (N=876;870;877;259)	24.8 (22.5 to 27.3)	25.8 (23.5 to 28.4)	25.8 (23.5 to 28.4)	8.7 (7.5 to 10)
Victoria, POST (N=878;871;877;259)	250.5 (230.8 to 272)	245.4 (226.9 to 265.4)	68.1 (61.9 to 74.9)	127.3 (109.4 to 148.1)
Yamagata, Day 0 (N=876;870;877;259)	57.9 (52 to 64.4)	58.4 (52.6 to 64.9)	65.9 (59.3 to 73.2)	7.7 (7 to 8.6)
Yamagata, POST (N=878;871;878;259)	512.5 (477.6 to 549.9)	197 (180.7 to 214.8)	579 (541.2 to 619.3)	192.7 (172.1 to 215.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects seroprotected against 4 strains of influenza disease

End point title	Number of subjects seroprotected against 4 strains of influenza disease
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End point description:

A seroprotected subject was defined as a vaccinated subject with serum Hemagglutination Inhibition titer $\geq 1:40$. The 4 assessed influenza strains were the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 flu strains.

End point type	Secondary
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End point timeframe:

At Day 0 and at 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	878	871	878	259
Units: Subjects				
H1N1, Day 0 (N=876;870;877;259)	480	496	477	87
H1N1, POST (N=878;871;878;259)	850	848	848	232
H3N2, Day 0 (N=876;870;876;259)	295	301	324	7
H3N2, POST (N=878;871;878;259)	816	808	819	193
Victoria, Day 0 (N=876;870;877;259)	388	404	400	28

Victoria, POST (N=878;871;877;259)	838	839	643	228
Yamagata, Day 0 (N=876;870;877;259)	578	583	622	22
Yamagata, POST (N=878;871;878;259)	869	805	873	250

Statistical analyses

No statistical analyses for this end point

Secondary: Seroconversion factor for Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease

End point title	Seroconversion factor for Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease
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End point description:

The seroconversion factor (SCF) was defined as the fold increase in serum Hemagglutination Inhibition (HI) geometric mean titers (GMTs) post vaccination (at Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects (POST)) compared to Day 0 (i.e. the geometric mean of the within-subject ratios of the post-vaccination reciprocal HI titer to the pre-vaccination reciprocal HI titer). The 4 assessed influenza strains were the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 (Yamagata) flu strains

End point type	Secondary
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End point timeframe:

At 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	876	870	877	259
Units: fold increase				
geometric mean (confidence interval 95%)				
H1N1, POST (N=876;870;877;259)	12.31 (11.34 to 13.35)	13.31 (12.28 to 14.43)	14.42 (13.27 to 15.66)	11.95 (10.52 to 13.59)
H3N2, POST (N=876;870;876;259)	7.94 (7.3 to 8.64)	7.37 (6.78 to 8.02)	7.78 (7.16 to 8.46)	10.94 (9.64 to 12.42)
Victoria, POST (N=876;870;876;259)	10.12 (9.23 to 11.09)	9.51 (8.64 to 10.45)	2.63 (2.47 to 2.81)	14.61 (12.84 to 16.63)
Yamagata, POST (N=876;870;877;259)	8.86 (8.12 to 9.66)	3.37 (3.14 to 3.62)	8.78 (8.05 to 9.58)	24.92 (21.98 to 28.26)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects seroprotected against 4 strains of influenza disease - age strata

End point title	Number of subjects seroprotected against 4 strains of influenza disease - age strata
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End point description:

End point type	Secondary
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End point timeframe:

At 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

End point values	GSK2282512A 1 (3-8 years) Group	GSK2282512A 1 (9-17 years) Group	Victoria strain Fluarix (3-8 years) Group	Victoria strain Fluarix (9-17 years) Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	425	453	424	447
Units: Subjects				
H1N1, Day 0 (N=423;453;423;447;424;453)	209	271	218	278
H1N1, POST (N=425;453;424;447;424;454)	405	445	412	436
H3N2, Day 0 (N=423;453;423;447;423;453)	161	134	174	127
H3N2, POST (N=425;453;424;447;424;454)	379	437	390	418
Victoria, Day 0 (N=423;453;423;447;424;453)	144	244	163	241
Victoria, POST (N=425;453;424;447;423;454)	398	440	406	433
Yamagata, Day 0 (N=423;453;423;447;424;453)	205	373	209	374
Yamagata, POST (N=425;453;424;447;424;454)	419	450	361	444

End point values	Yamagata strain Fluarix (3-8 years) Group	Yamagata strain Fluarix (9-17 years) Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	424	454		
Units: Subjects				
H1N1, Day 0 (N=423;453;423;447;424;453)	207	270		
H1N1, POST (N=425;453;424;447;424;454)	405	443		
H3N2, Day 0 (N=423;453;423;447;423;453)	168	156		
H3N2, POST (N=425;453;424;447;424;454)	389	430		
Victoria, Day 0 (N=423;453;423;447;424;453)	150	250		
Victoria, POST (N=425;453;424;447;423;454)	271	372		
Yamagata, Day 0 (N=423;453;423;447;424;453)	220	402		
Yamagata, POST (N=425;453;424;447;424;454)	420	453		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects seroprotected against 4 strains of influenza disease - 6 to 35 Months old

End point title	Number of subjects seroprotected against 4 strains of influenza disease - 6 to 35 Months old ^[2]
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End point description:

A seroprotected subject was defined as a vaccinated subject with serum Hemagglutination Inhibition titer $\geq 1:40$. The 4 assessed influenza strains were the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 flu strains. Subjects were assessed according to 3 age categories, 3-8 years, 9-17 years and 6-35 months.

End point type	Secondary
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End point timeframe:

At Day 0 and at 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The analysis was performed only on subjects between 6 and 35 months old, included in the Control Group.

End point values	GSK2282512A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	259			
Units: Subjects				
H1N1, Day 0 (N=423;453;423;447;424;453;259)	87			
H1N1, POST (N=425;453;424;447;424;454;259)	232			
H3N2, Day 0 (N=423;453;423;447;423;453;259)	7			
H3N2, POST (N=425;453;424;447;424;454;259)	193			
Victoria, Day 0 (N=423;453;423;447;424;453;259)	28			
Victoria, POST (N=425;453;424;447;423;454;259)	228			
Yamagata, Day 0 (N=423;453;423;447;424;453;259)	22			
Yamagata, POST (N=425;453;424;447;424;454;259)	250			

Statistical analyses

Secondary: Seroconversion factor for Hemagglutination Inhibition antibodies against 4 strains of influenza disease - 6-35 Months

End point title	Seroconversion factor for Hemagglutination Inhibition antibodies against 4 strains of influenza disease - 6-35 Months ^[3]
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End point description:

The seroconversion factor (SCF) was defined as the fold increase in serum Hemagglutination Inhibition (HI) geometric mean titers (GMTs) post vaccination compared to Day 0 (i.e. the geometric mean of the within-subject ratios of the post-vaccination reciprocal HI titer to the pre-vaccination reciprocal HI titer). The 4 assessed influenza strains were the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 (Yamagata) flu strains.

End point type	Secondary
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End point timeframe:

At 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The analysis was performed only on subjects between 6 and 35 months old, included in the Control Group.

End point values	GSK2282512A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	259			
Units: fold increase				
geometric mean (confidence interval 95%)				
H1N1, POST (N=876;870;877;259)	11.95 (10.52 to 13.59)			
H3N2, POST (N=876;870;876;259)	10.94 (9.64 to 12.42)			
Victoria, POST (N=876;870;876;259)	14.61 (12.84 to 16.63)			
Yamagata, POST (N=876;870;877;259)	24.92 (21.98 to 28.26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms after vaccination

End point title	Number of subjects with any and grade 3 solicited local symptoms after vaccination
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End point description:

Solicited local symptoms assessed were pain, redness and swelling. Any was defined as any solicited local symptom reported irrespective of intensity grade. Grade 3 pain for subjects < 5 years of age = Cried when limb was moved/spontaneously painful; Grade 3 pain for subjects ≥ 5 years of age = Significant pain at rest, pain that prevented normal everyday activities. Grade 3 redness and swelling were defined as redness/swelling above 100 millimeters (mm).

End point type	Secondary
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End point timeframe:

During the 7-day follow-up period (Days 0-6) after vaccination

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	913	912	916	294
Units: Subjects				
Any pain	637	538	542	148
Grade 3 pain	35	21	26	6
Any redness	57	38	36	24
Grade 3 redness	1	0	0	2
Any swelling	64	40	39	18
Grade 3 swelling	1	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of days with solicited local symptoms after vaccination

End point title	Number of days with solicited local symptoms after vaccination
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End point description:

Duration was assessed via tabulation of the number of days with local symptoms of any grade after vaccination with Dose 1 and Dose 2 respectively. Solicited local symptoms assessed for duration were pain, redness and swelling.

End point type	Secondary
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End point timeframe:

During the 7-day follow-up period (Days 0-6) after vaccination

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	597	497	510	131
Units: Days				
median (inter-quartile range (Q1-Q3))				
Pain, Dose 1 (N=597;497;510;131)	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	1 (1 to 2)
Pain, Dose 2 (N=169;151;141;76)	2 (1 to 2)	2 (1 to 2)	2 (1 to 2)	2 (1 to 2)
Redness, Dose 1 (N=48;29;32;13)	2 (1 to 3)	1 (1 to 2)	1 (1 to 2)	1 (1 to 5)
Redness, Dose 2 (N=13;11;10;14)	2 (1 to 3)	1 (1 to 3)	1.5 (1 to 3)	2.5 (1 to 4)
Swelling, Dose 1 (N=57;30;35;10)	2 (1 to 2)	2 (1 to 2)	2 (1 to 2)	1.5 (1 to 3)
Swelling, Dose 2 (N=12;15;7;11)	2.5 (2 to 4)	2 (1 to 2)	2 (1 to 2)	3 (2 to 4)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects below 5 years of age with any, grade 3 and related solicited general symptoms

End point title	Number of subjects below 5 years of age with any, grade 3 and related solicited general symptoms
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End point description:

Symptoms assessed were drowsiness, irritability, loss of appetite and temperature. Any = Incidence of a particular symptom regardless of intensity grade or relationship to vaccination. Any temperature = Axillary temperature ≥ 38.0 degrees Celsius ($^{\circ}\text{C}$). Grade 3 temperature = Axillary temperature $\geq 39.0^{\circ}\text{C}$. Grade 3 irritability = Crying that could not be comforted/ preventing normal activity. Grade 3 drowsiness = Drowsiness preventing normal activity. Grade 3 loss of appetite = Not eating at all. Related = A general symptom assessed by the investigator as causally related to vaccination.

End point type	Secondary
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End point timeframe:

During the 7-day follow-up period (Days 0-6) after vaccination

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	185	187	189	292
Units: Subjects				
Any drowsiness	46	47	51	102
Grade 3 drowsiness	0	3	1	7
Related drowsiness	34	40	42	93
Any irritability	59	44	48	141
Grade 3 irritability	3	0	3	14
Related irritability	45	36	45	130
Any loss of appetite	40	41	35	93
Grade 3 loss of appetite	0	6	3	5
Related loss of appetite	21	28	24	73
Any temperature	15	16	15	27
Grade 3 temperature	3	5	5	6
Related temperature	6	10	6	18

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects 5 years of age and above with any, grade 3 and related solicited general symptoms

End point title	Number of subjects 5 years of age and above with any, grade 3 and related solicited general symptoms ^[4]
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End point description:

Solicited general symptoms assessed were fatigue, gastrointestinal symptoms, headache, joint pain at other location, muscle aches, shivering and temperature. Any = Incidence of a particular symptom regardless of intensity grade or relationship to vaccination. Any temperature = axillary temperature $\geq 38.0^{\circ}\text{C}$. Grade 3 temperature = axillary temperature $\geq 39.0^{\circ}\text{C}$. Grade 3 symptom = Symptom that prevented normal activity. Related = A general symptom assessed by the investigator as causally related to vaccination.

End point type	Secondary
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End point timeframe:

During the 7-day follow-up period (Days 0-6) after vaccination

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The analysis was done only on subjects above 5 years of age from the study pooled groups.

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	727	725	726	
Units: Subjects				
Any fatigue	173	177	177	
Grade 3 fatigue	6	13	8	
Related fatigue	143	149	134	
Any gastrointestinal symptoms	80	82	72	
Grade 3 gastrointestinal symptoms	9	8	6	
Related gastrointestinal symptoms	55	51	37	
Any headache	170	171	157	
Grade 3 headache	8	9	10	
Related headache	134	134	116	
Any joint pain at other location	103	95	81	
Grade 3 joint pain at other location	4	5	1	
Related joint pain at other location	82	80	67	
Any muscle aches	222	194	193	
Grade 3 muscle aches	6	5	9	
Related muscle aches	202	178	170	
Any shivering	55	51	53	
Grade 3 shivering	4	10	4	
Related shivering	45	35	41	
Any temperature	26	33	20	
Grade 3 temperature	5	8	2	
Related temperature	16	18	13	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of days with solicited general symptoms after vaccination in subjects below 5 years of age

End point title	Number of days with solicited general symptoms after vaccination in subjects below 5 years of age
End point description: Duration was assessed via tabulation of the number of days with local symptoms of any grade after vaccination with Dose 1 and Dose 2, respectively. Solicited general symptoms assessed for duration in subjects below 5 years of age were drowsiness, irritability and loss of appetite.	
End point type	Secondary
End point timeframe: During the 7-day follow-up period (Days 0-6) after vaccination	

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	37	44	120
Units: Days				
median (inter-quartile range (Q1-Q3))				
Drowsiness, Dose 1 (N=39;37;44;85)	1 (1 to 2)	2 (1 to 2)	1 (1 to 2)	2 (1 to 3)
Drowsiness, Dose 2 (N=16;18;17;45)	1 (1 to 1.5)	1 (1 to 2)	2 (1 to 3)	2 (1 to 3)
Irritability, Dose 1 (N=48;31;41;120)	1 (1 to 2)	2 (1 to 4)	2 (1 to 3)	2 (1 to 3)
Irritability, Dose 2 (N=25;22;16;74)	1 (1 to 2)	2 (1 to 3)	2 (1 to 3.5)	2 (1 to 3)
Loss of appetite, Dose 1 (N=32;30;25;64)	1 (1 to 2)	2 (1 to 3)	1 (1 to 2)	2 (1 to 3)
Loss of appetite, Dose 2 (N=13;15;14;48)	2 (1 to 3)	2 (1 to 4)	3 (1 to 5)	2 (1 to 3)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of days with solicited general symptoms after vaccination in subjects 5 years of age and above

End point title	Number of days with solicited general symptoms after vaccination in subjects 5 years of age and above ^[5]
End point description: Duration was assessed via tabulation of the number of days with local symptoms of any grade after vaccination with Dose 1 and Dose 2, respectively. Solicited general symptoms assessed for duration in subjects 5 years of age and above were fatigue, gastrointestinal symptoms, headache, joint pain at other location, muscle aches and shivering.	
End point type	Secondary
End point timeframe: During the 7-day follow-up period (Days 0-6) after vaccination	

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was done on the four pooled groups of the study.

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	207	180	179	
Units: Days				
median (inter-quartile range (Q1-Q3))				
Fatigue, Dose 1 (N=161;171;167)	2 (1 to 3)	1 (1 to 3)	2 (1 to 3)	
Fatigue, Dose 2 (N=27;19;19)	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	
Gastrointestinal symptoms, Dose 1 (N=70;70;65)	1.5 (1 to 3)	1 (1 to 3)	1 (1 to 2)	
Gastrointestinal symptoms, Dose 2 (N=17;16;9)	1 (1 to 2)	1.5 (1 to 2)	2 (1 to 2)	
Headache, Dose 1 (160;160;146)	2 (1 to 2)	1 (1 to 2)	2 (1 to 3)	
Headache, Dose 2 (20;19;17)	1.5 (1 to 2.5)	1 (1 to 2)	1 (1 to 2)	
Joint pain at other location, Dose 1 (N=94;86;76)	2 (1 to 2)	2 (1 to 3)	1.5 (1 to 3)	
Joint pain at other location, Dose 2 (N=21;13;10)	2 (1 to 2)	1 (1 to 2)	1 (1 to 2)	
Muscle aches, Dose 1 (N=207;180;179)	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	
Muscle aches, Dose 2 (N=44;27;30)	1 (1 to 2)	1 (1 to 2)	2 (1 to 2)	
Shivering, Dose 1 (N=51;50;50)	1 (1 to 3)	2 (1 to 2)	1 (1 to 3)	
Shivering, Dose 2 (N=8;1;4)	1.5 (1 to 2)	1 (1 to 1)	2 (1 to 2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of days with fever in all subjects regardless of their age after vaccination

End point title	Number of days with fever in all subjects regardless of their age after vaccination
End point description: Duration for fever was assessed via tabulation of the number of days with local symptoms of fever (axillary temperature $\geq 38^{\circ}\text{C}$) after vaccination with Dose 1 and Dose 2, respectively.	
End point type	Secondary
End point timeframe: During the 7-day follow-up period (Days 0-6) after vaccination	

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	43	26	16
Units: Days				
median (inter-quartile range (Q1-Q3))				
Fever, Dose 1 (N=25;43;26;16)	1 (1 to 1)	1 (1 to 2)	1.5 (1 to 2)	1 (1 to 2)
Fever, Dose 2 (N=17;7;9;12)	2 (1 to 3)	1 (1 to 2)	1 (1 to 2)	1.5 (1 to 2.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related unsolicited adverse events (AEs)

End point title	Number of subjects with any, grade 3 and related unsolicited adverse events (AEs)
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End point description:

Unsolicited AE covers any AE reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any unsolicited AE(s) = Occurrence of any unsolicited symptom regardless of intensity grade or relation to vaccination. Grade 3 unsolicited AE = Occurrence of any unsolicited AE that prevented normal activities. Related unsolicited AE(s) = Occurrence of an unsolicited AE assessed by the investigator to be causally related to vaccination.

End point type	Secondary
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End point timeframe:

During the 28-day follow-up period (Day 0-27) after vaccination

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	932	929	932	301
Units: Subjects				
Any unsolicited AE(s)	283	291	275	160
Grade 3 unsolicited AE(s)	40	41	35	24
Related unsolicited AE(s)	44	47	44	43

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and related potential immune-mediated diseases (pIMDs) after vaccination

End point title	Number of subjects with any and related potential immune-mediated diseases (pIMDs) after vaccination
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End point description:

Potential immune-mediated diseases (pIMDs) are a subset of adverse events that include both clearly autoimmune diseases and also other inflammatory and/or neurologic disorders which may or may not have an autoimmune etiology. Any pIMD(s) = Occurrence of any pIMD(s) regardless of intensity grade or relation to vaccination. Relationship to vaccination was not assessed for pIMDs.

End point type	Secondary
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End point timeframe:

During the entire study period (from Day 0 to Day 180)

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	932	929	932	301
Units: Subjects				
Any pIMD(s)	0	1	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and related medically-attended adverse events (MAEs) after vaccination

End point title	Number of subjects with any and related medically-attended adverse events (MAEs) after vaccination
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End point description:

Medically-attended adverse events (MAEs) were non-serious and serious events leading to an otherwise unscheduled visit to or from medical personnel for any reason, including emergency room visits. If a medically-attended adverse event was leading to hospitalization (or met any other criterion for serious adverse event (SAE)), it was reported as SAE. Any MAE(s) = Occurrence of any MAE(s) regardless of intensity grade or relation to vaccination. Relationship to vaccination was not assessed for MAEs.

End point type	Secondary
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End point timeframe:

During the entire study period (from Day 0 to Day 180)

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	932	929	932	301
Units: Subjects				
Any MAE(s)	346	335	350	147

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and related serious adverse events (SAEs)

End point title	Number of subjects with any and related serious adverse events (SAEs)
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End point description:

SAEs assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization, result in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subject. Any SAE(s) = Occurrence of any SAE(s) regardless of intensity grade or relation to vaccination. Related SAE(s)= Occurrence of any SAE(s) assessed by the investigator as causally related to vaccination.

End point type	Secondary
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End point timeframe:

During the entire study period (from Day 0 to Day 180)

End point values	GSK2282512A 1 Group	Victoria strain Fluarix Group	Yamagata strain Fluarix Group	GSK2282512A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	932	929	932	301
Units: Subjects				
Any SAE(s)	3	6	5	7
Related SAE(s)	0	0	1	2

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease - 6 to 35 Months old

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease - 6 to 35 Months old ^[6]
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End point description:

Titers are presented as geometric mean titers (GMTs). The reference cut-off value was the seropositivity cut-off of 1:10. Antibodies assessed were antibodies against the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 (Yamagata) flu strains. Subjects were assessed according to 3 age categories, 3-8 years, and 6-35 months.

End point type	Secondary
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End point timeframe:

At Day 0 and at 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The analysis was performed only on subjects between 6 and 35 months old, included in the Control Group.

End point values	GSK2282512A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	259			
Units: titer				
geometric mean (confidence interval 95%)				
H1N1, Day 0 (N=423;423;424;259)	16.8 (13.9 to 20.3)			

H1N1, POST (N=425;424;424;259)	200.9 (166.6 to 242.2)			
H3N2, Day 0 (N=423;423;423;259)	5.6 (5.3 to 6)			
H3N2, POST (N=425;424;424;259)	61.4 (53.8 to 70)			
Victoria, Day 0 (N=423;423;424;259)	8.7 (7.5 to 10)			
Victoria, POST (N=425;424;423;259)	127.3 (109.4 to 148.1)			
Yamagata, Day 0 (N=423;423;424;259)	7.7 (7 to 8.6)			
Yamagata, POST (N=425;424;424;259)	192.7 (172.1 to 215.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease - age strata

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease - age strata
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End point description:

Titers are presented as geometric mean titers (GMTs). The reference cut-off value was the seropositivity cut-off of 1:10. Antibodies assessed were antibodies against the A/California/7/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (Victoria) and B/Florida/4/2006 (Yamagata) flu strains. Subjects were assessed according to 3 age categories, 3-8 years, and 6-35 months.

End point type	Secondary
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End point timeframe:

At Day 0 and at 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

End point values	GSK2282512A 1 (3-8 years) Group	GSK2282512A 1 (9-17 years) Group	Victoria strain Fluarix (3-8 years) Group	Victoria strain Fluarix (9-17 years) Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	425	453	424	447
Units: titre				
geometric mean (confidence interval 95%)				
H1N1, Day 0 (N=423;453;423;447;424;453)	24.7 (21.6 to 28.3)	34.6 (30.6 to 39.2)	26.9 (23.5 to 30.9)	38.2 (33.8 to 43.1)
H1N1, POST (N=425;453;424;447;424;454)	310.5 (274.9 to 350.6)	419.5 (379.8 to 463.4)	382.7 (339.4 to 431.6)	478.2 (431.4 to 530)
H3N2, Day 0 (N=423;453;423;447;423;453)	19.7 (17.4 to 22.4)	16.7 (15 to 18.7)	21.2 (18.6 to 24.2)	17 (15.3 to 19)
H3N2, POST (N=425;453;424;447;424;454)	138.2 (123.7 to 154.5)	149.1 (137.3 to 162)	144.4 (130.6 to 159.7)	135.2 (123.5 to 148)
Victoria, Day 0 (N=423;453;423;447;424;453)	18.3 (15.8 to 21.1)	32.9 (29 to 37.4)	20.2 (17.6 to 23.3)	32.5 (28.7 to 36.8)
Victoria, POST (N=425;453;424;447;423;454)	194.4 (171.3 to 220.7)	317.8 (287.1 to 351.8)	197.4 (175.9 to 221.6)	301.7 (272.2 to 334.3)
Yamagata, Day 0 (N=423;453;423;447;424;453)	27.4 (23.8 to 31.7)	116.2 (102.2 to 132.1)	29.5 (25.6 to 34)	111.6 (98.3 to 126.8)

Yamagata, POST (N=425;453;424;447;424;454)	363.4 (327.8 to 402.9)	707.5 (648.7 to 771.5)	103.2 (91.7 to 116.1)	363.7 (330.4 to 400.3)
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End point values	Yamagata strain Fluarix (3-8 years) Group	Yamagata strain Fluarix (9-17 years) Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	424	454		
Units: titre				
geometric mean (confidence interval 95%)				
H1N1, Day 0 (N=423;453;423;447;424;453)	24.5 (21.5 to 27.8)	34.2 (30.3 to 38.6)		
H1N1, POST (N=425;453;424;447;424;454)	356.2 (316.5 to 400.8)	490.3 (443.7 to 541.7)		
H3N2, Day 0 (N=423;453;423;447;423;453)	20.2 (17.8 to 23)	18.6 (16.6 to 20.9)		
H3N2, POST (N=425;453;424;447;424;454)	147.9 (133.3 to 164.1)	153.9 (140.7 to 168.4)		
Victoria, Day 0 (N=423;453;423;447;424;453)	18.4 (16 to 21.1)	35.4 (31.3 to 40.1)		
Victoria, POST (N=425;453;424;447;423;454)	52.6 (45.2 to 61.2)	86.6 (77.4 to 96.9)		
Yamagata, Day 0 (N=423;453;423;447;424;453)	29.5 (25.5 to 34.1)	139.6 (124.6 to 156.4)		
Yamagata, POST (N=425;453;424;447;424;454)	416.7 (374.5 to 463.7)	787.1 (731.3 to 847.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects seroconverted against 4 strains of influenza disease - 6-35 months old

End point title	Number of subjects seroconverted against 4 strains of influenza disease - 6-35 months old ^[7]
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End point description:

End point type	Secondary
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End point timeframe:

At 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was performed only on subjects between 6 and 35 months old, included in the Control Group.

End point values	GSK2282512A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	259			
Units: Subjects				
H1N1, POST	220			
H3N2, POST	189			
Victoria, POST	219			
Yamagata, POST	243			

Statistical analyses

No statistical analyses for this end point

Secondary: Seroconversion factor for Hemagglutination Inhibition antibodies against 4 strains of influenza disease - age strata

End point title	Seroconversion factor for Hemagglutination Inhibition antibodies against 4 strains of influenza disease - age strata
End point description:	
End point type	Secondary
End point timeframe:	At 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

End point values	GSK2282512A 1 (3-8 years) Group	GSK2282512A 1 (9-17 years) Group	Victoria strain Fluarix (3-8 years) Group	Victoria strain Fluarix (9-17 years) Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	453	423	447
Units: fold increase				
geometric mean (confidence interval 95%)				
H1N1, POST (N=423;453;423;447;424;453)	12.5 (11.31 to 13.82)	12.12 (10.67 to 13.77)	14.2 (12.83 to 15.71)	12.52 (11.07 to 14.17)
H3N2, POST (N=423;453;423;447;423;453)	7.02 (6.3 to 7.84)	8.91 (7.85 to 10.11)	6.82 (6.09 to 7.64)	7.94 (7.02 to 8.97)
Victoria, POST (N=423;453;423;447;423;453)	10.64 (9.41 to 12.02)	9.65 (8.42 to 11.07)	9.75 (8.61 to 11.04)	9.28 (8.04 to 10.71)
Yamagata, POST (N=423;453;423;447;424;453)	13.23 (11.74 to 14.9)	6.09 (5.42 to 6.84)	3.49 (3.18 to 3.84)	3.26 (2.93 to 3.62)

End point values	Yamagata strain Fluarix (3-8 years) Group	Yamagata strain Fluarix (9-17 years) Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	424	453		

Units: fold increase				
geometric mean (confidence interval 95%)				
H1N1, POST (N=423;453;423;447;424;453)	14.56 (13.2 to 16.05)	14.29 (12.52 to 16.31)		
H3N2, POST (N=423;453;423;447;423;453)	7.29 (6.51 to 8.16)	8.27 (7.32 to 9.34)		
Victoria, POST (N=423;453;423;447;423;453)	2.85 (2.58 to 3.16)	2.44 (2.25 to 2.65)		
Yamagata, POST (N=423;453;423;447;424;453)	14.11 (12.57 to 15.84)	5.63 (5.02 to 6.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects seroconverted against 4 strains of influenza disease - age strata

End point title	Number of subjects seroconverted against 4 strains of influenza disease - age strata
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End point description:

End point type	Secondary
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End point timeframe:

At 28 days after administration of the last vaccine dose (Day 28 for Primed Subjects and at Day 56 for Unprimed Subjects) (POST)

End point values	GSK2282512A 1 (3-8 years) Group	GSK2282512A 1 (9-17 years) Group	Victoria strain Fluarix (3-8 years) Group	Victoria strain Fluarix (9-17 years) Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	453	423	447
Units: Subjects				
H1N1, POST (N=423;453;423;447;424;453)	374	365	390	365
H3N2, POST (N=423;453;423;447;423;453)	291	323	282	308
Victoria, POST (N=423;453;423;447;423;453)	329	324	326	296
Yamagata, POST (N=423;453;423;447;424;453)	366	293	181	178

End point values	Yamagata strain Fluarix (3-8 years) Group	Yamagata strain Fluarix (9-17 years) Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	424	453		
Units: Subjects				

H1N1, POST (N=423;453;423;447;424;453)	380	370		
H3N2, POST (N=423;453;423;447;423;453)	296	314		
Victoria, POST (N=423;453;423;447;423;453)	133	129		
Yamagata, POST (N=423;453;423;447;424;453)	372	272		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events were assessed from Day 0 to Day 180. Systematically and non-systematically assessed frequent adverse events (AEs) were assessed during a 7-day and 28-day post-vaccination period, respectively.

Adverse event reporting additional description:

For the systematically-assessed other non-serious AEs, the number of participants at risk included those from Total Vaccinated cohort whose symptom sheet had been completed.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Reporting groups

Reporting group title	Victoria strain Fluarix Group
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Reporting group description:

Subjects, 3 to 17 years old, received 1 dose of Fluarix™ VB vaccine containing the Victoria lineage B flu strain at Day 0 or 2 doses of Fluarix™ VB vaccine at Day 0 and Day 28. The Fluarix™ VB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	GSK2282512A 2 Group
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Reporting group description:

Subjects, 6 to 35 months old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm for subjects ≥12 months of age and into the antero-lateral region of the left thigh for infants <12 months of age.

Reporting group title	Yamagata strain Fluarix Group
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Reporting group description:

Subjects, 3 to 17 years old, received 1 dose of Fluarix™ YB vaccine containing the Yamagata lineage B flu strain at Day 0 or 2 doses of Fluarix™ YB vaccine at Day 0 and Day 28. The Fluarix™ YB vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	GSK2282512A 1 Group
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Reporting group description:

Subjects, 3 to 17 years old, received 1 dose of GSK2282512A vaccine at Day 0 or 2 doses of GSK2282512A vaccine at Day 0 and Day 28. The GSK2282512A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm.

Serious adverse events	Victoria strain Fluarix Group	GSK2282512A 2 Group	Yamagata strain Fluarix Group
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 929 (0.65%)	7 / 301 (2.33%)	5 / 932 (0.54%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	0 / 932 (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

Facial bones fracture			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 929 (0.00%)	1 / 301 (0.33%)	0 / 932 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic brain injury			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Congenital, familial and genetic disorders			
Vitello-intestinal duct remnant			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	0 / 932 (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
Nervous system disorders			
Febrile convulsion			

subjects affected / exposed	0 / 929 (0.00%)	1 / 301 (0.33%)	0 / 932 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Grand mal convulsion			
subjects affected / exposed	0 / 929 (0.00%)	1 / 301 (0.33%)	0 / 932 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Anxiety			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Suicidal ideation			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	0 / 932 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Hypersensitivity			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Eye disorders			

Conjunctivitis			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 929 (0.00%)	3 / 301 (1.00%)	0 / 932 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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			
Gastroenteritis			
subjects affected / exposed	1 / 929 (0.11%)	1 / 301 (0.33%)	0 / 932 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			

subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	0 / 929 (0.00%)	1 / 301 (0.33%)	0 / 932 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 929 (0.11%)	0 / 301 (0.00%)	0 / 932 (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
Pneumonia viral			
subjects affected / exposed	0 / 929 (0.00%)	1 / 301 (0.33%)	0 / 932 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 929 (0.00%)	1 / 301 (0.33%)	0 / 932 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypovolaemia			
subjects affected / exposed	0 / 929 (0.00%)	0 / 301 (0.00%)	1 / 932 (0.11%)
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	GSK2282512A 1 Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 932 (0.32%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 932 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Traumatic brain injury			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Vitello-intestinal duct remnant			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			

subjects affected / exposed	1 / 932 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Grand mal convulsion			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	1 / 932 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anxiety			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	1 / 932 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Hypersensitivity			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			

subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lobar pneumonia			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypovolaemia			
subjects affected / exposed	0 / 932 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Victoria strain Fluarix Group	GSK2282512A 2 Group	Yamagata strain Fluarix Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	538 / 929 (57.91%)	148 / 301 (49.17%)	542 / 932 (58.15%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	538 / 912 (58.99%)	148 / 294 (50.34%)	542 / 916 (59.17%)
occurrences (all)	538	148	542
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	40 / 912 (4.39%)	18 / 294 (6.12%)	39 / 916 (4.26%)
occurrences (all)	40	18	39
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	47 / 187 (25.13%)	102 / 292 (34.93%)	51 / 189 (26.98%)
occurrences (all)	47	102	51
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	44 / 187 (23.53%)	141 / 292 (48.29%)	48 / 189 (25.40%)
occurrences (all)	44	141	48
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed ^[5]	41 / 187 (21.93%)	93 / 292 (31.85%)	35 / 189 (18.52%)
occurrences (all)	41	93	35
Temperature			
alternative assessment type: Systematic			
subjects affected / exposed ^[6]	16 / 187 (8.56%)	27 / 292 (9.25%)	15 / 189 (7.94%)
occurrences (all)	16	27	15
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed ^[7]	177 / 725 (24.41%)	0 / 301 (0.00%)	177 / 726 (24.38%)
occurrences (all)	177	0	177

Gastrointestinal alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all)	82 / 725 (11.31%) 82	0 / 301 (0.00%) 0	72 / 726 (9.92%) 72
Headache alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all)	171 / 725 (23.59%) 171	0 / 301 (0.00%) 0	157 / 726 (21.63%) 157
Joint pain at other location alternative assessment type: Systematic subjects affected / exposed ^[10] occurrences (all)	95 / 725 (13.10%) 95	0 / 301 (0.00%) 0	81 / 726 (11.16%) 81
Muscle aches alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all)	194 / 725 (26.76%) 194	0 / 301 (0.00%) 0	193 / 726 (26.58%) 193
Shivering alternative assessment type: Systematic subjects affected / exposed ^[12] occurrences (all)	51 / 725 (7.03%) 51	0 / 301 (0.00%) 0	53 / 726 (7.30%) 53
Pyrexia subjects affected / exposed occurrences (all)	16 / 929 (1.72%) 16	21 / 301 (6.98%) 21	13 / 932 (1.39%) 13
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	10 / 929 (1.08%) 10	20 / 301 (6.64%) 20	7 / 932 (0.75%) 7
Redness alternative assessment type: Systematic subjects affected / exposed ^[13] occurrences (all)	38 / 912 (4.17%) 38	24 / 294 (8.16%) 24	36 / 916 (3.93%) 36
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	38 / 929 (4.09%) 38	34 / 301 (11.30%) 34	49 / 932 (5.26%) 49

Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	30 / 929 (3.23%) 30	24 / 301 (7.97%) 24	33 / 932 (3.54%) 33
Nasopharyngitis subjects affected / exposed occurrences (all)	47 / 929 (5.06%) 47	14 / 301 (4.65%) 14	43 / 932 (4.61%) 43
Rhinorrhoea subjects affected / exposed occurrences (all)	12 / 929 (1.29%) 12	33 / 301 (10.96%) 33	19 / 932 (2.04%) 19

Non-serious adverse events	GSK2282512A 1 Group		
Total subjects affected by non-serious adverse events subjects affected / exposed	637 / 932 (68.35%)		
General disorders and administration site conditions			
Pain alternative assessment type: Systematic subjects affected / exposed ^[1] occurrences (all)	637 / 913 (69.77%) 637		
Swelling alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all)	64 / 913 (7.01%) 64		
Drowsiness alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	46 / 185 (24.86%) 46		
Irritability alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	59 / 185 (31.89%) 59		
Loss of appetite alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all)	40 / 185 (21.62%) 40		
Temperature			

<p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p>	<p>15 / 185 (8.11%)</p> <p>15</p>		
<p>Fatigue</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p>	<p>173 / 727 (23.80%)</p> <p>173</p>		
<p>Gastrointestinal</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p>	<p>80 / 727 (11.00%)</p> <p>80</p>		
<p>Headache</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[9]</p> <p>occurrences (all)</p>	<p>170 / 727 (23.38%)</p> <p>170</p>		
<p>Joint pain at other location</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[10]</p> <p>occurrences (all)</p>	<p>103 / 727 (14.17%)</p> <p>103</p>		
<p>Muscle aches</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[11]</p> <p>occurrences (all)</p>	<p>222 / 727 (30.54%)</p> <p>222</p>		
<p>Shivering</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[12]</p> <p>occurrences (all)</p>	<p>55 / 727 (7.57%)</p> <p>55</p>		
<p>Pyrexia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>19 / 932 (2.04%)</p> <p>19</p>		
<p>Gastrointestinal disorders</p> <p>Diarrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Redness</p>	<p>11 / 932 (1.18%)</p> <p>11</p>		

alternative assessment type: Systematic subjects affected / exposed ^[13] occurrences (all)	57 / 913 (6.24%) 57		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	53 / 932 (5.69%) 53		
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all)	36 / 932 (3.86%) 36 48 / 932 (5.15%) 48 17 / 932 (1.82%) 17		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed solely on subjects with symptom sheet completed for the reported specific symptom.

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