



Clinical trial results:

A phase III, double-blind, randomized study to evaluate the immunogenicity and safety of GSK Biologicals' quadrivalent influenza vaccine compared to GSK Biologicals' trivalent influenza vaccine administered intramuscularly in children aged 3 to 17 years and to describe the safety and immunogenicity of GSK Biologicals' quadrivalent influenza vaccine in children aged 6 to 35 months.

Summary

EudraCT number	2010-021032-34
Trial protocol	DE FR CZ Outside EU/EEA
Global end of trial date	15 June 2011

Results information

Result version number	v2 (current)
This version publication date	14 July 2022
First version publication date	04 April 2015
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Correction of full data set and alignment between registries.

Trial information

Trial identification

Sponsor protocol code	113275
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01196988
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium,
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-000817-PIP02-11
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	16 September 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 June 2011
Global end of trial reached?	Yes
Global end of trial date	15 June 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

•To evaluate the immunological non-inferiority (in terms of Geometric Mean Titre (GMT) and Seroconversion Rate (SCR)) of GSK2321138A vaccine versus Fluarix and GSK2604409A vaccine in children (3 to 17 years) at 28 days (primed subjects) or 56 days (unprimed subjects) following first vaccination (28 days after completion of the immunization series).

Criteria to conclude non-inferiority:

- The test of non-inferiority will be based on the analysis of the entire age range in each treatment group. Non-inferiority will be concluded if, for the three strains contained in each TIV formulation:
- The upper limit of the two-sided 95% confidence interval (CI) of the GMT ratio (TIV-1 (Fluarix) / D-QIV and TIV-2 / D-QIV) after completion of the vaccination series does not exceed 1.5 and
- The upper limit of the two-sided 95% CI for the difference in SCR (TIV-1 (Fluarix) minus D-QIV and TIV-2 minus D-QIV) does not exceed 10% for the three strains contained in each TIV formulation

Protection of trial subjects:

All subjects were supervised for 30 min after vaccination/product administration with appropriate medical treatment readily available. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines/products. Subjects were followed-up for 125 days after the last vaccination/product administration.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 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	United States: 1065
Country: Number of subjects enrolled	Czech Republic: 235
Country: Number of subjects enrolled	France: 183
Country: Number of subjects enrolled	Germany: 707
Country: Number of subjects enrolled	Philippines: 837
Worldwide total number of subjects	3027
EEA total number of subjects	1125

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)	277
Children (2-11 years)	2183
Adolescents (12-17 years)	567
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were differentiated according to their priming status. Primed subjects had received at least 1 dose of an influenza A (H1N1) 2009 monovalent vaccine and had received 2 doses of seasonal influenza in the last season or had received at least 1 dose prior to last season. Unprimed subjects had not.

Pre-assignment

Screening details:

3015 subjects out of the 3027 who were enrolled in the study were vaccinated. Remaining subjects were not included in the participant flow as started as they failed to meet protocol criteria. The treatment was stratified by age strata: 3-8 and 9-17 years. Another arm evaluates the GSK2321138A vaccine for children aged 6-17 and 18-35 months.

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, Monitor, Data analyst, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK2321138A 1 Group

Arm description:

Subjects aged 3-17 years received if primed, 1 dose of GSK2321138A at Day 0 and if unprimed, 2 doses of GSK2321138A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.

Arm type	Experimental
Investigational medicinal product name	Influenza vaccine GSK2321138A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

intramuscular injections

Arm title	Fluarix Group
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Arm description:

Subjects aged 3-17 years received if primed, 1 dose of Fluarix at Day 0 and if unprimed, 2 doses of Fluarix at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.

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

Dosage and administration details:

intramuscular injections

Arm title	GSK2604409A Group
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Arm description:

Subjects aged 3-17 years received if primed, 1 dose of GSK2604409A at Day 0 and if unprimed, 2 doses of GSK2604409A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.

Arm type	Active comparator
Investigational medicinal product name	Influenza vaccine GSK2604409A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: intramuscular injections	
Arm title	GSK2321138A 2 Group

Arm description:

Subjects aged 6-35 months received if primed, 1 dose of GSK2321138A at Day 0 and if unprimed, 2 doses of GSK2321138A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.

Arm type	Experimental
Investigational medicinal product name	Influenza vaccine GSK2321138A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular and intravenous use
Dosage and administration details: intramuscular injections	

Number of subjects in period 1^[1]	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group
Started	915	912	911
Completed	891	880	886
Not completed	24	32	25
Consent withdrawn by subject	5	1	4
Adverse event, non-fatal	1	2	-
Unspecified	2	-	-
Lost to follow-up	16	29	21

Number of subjects in period 1^[1]	GSK2321138A 2 Group
Started	277
Completed	276
Not completed	1
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Unspecified	-

Lost to follow-up	1
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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: 3015 subjects out of the 3027 who were enrolled in the study were vaccinated. Remaining subjects were not included in the participant flow as started as they failed to meet protocol criteria.

Baseline characteristics

Reporting groups

Reporting group title	GSK2321138A 1 Group
Reporting group description:	
Subjects aged 3-17 years received if primed, 1 dose of GSK2321138A at Day 0 and if unprimed, 2 doses of GSK2321138A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.	
Reporting group title	Fluarix Group
Reporting group description:	
Subjects aged 3-17 years received if primed, 1 dose of Fluarix at Day 0 and if unprimed, 2 doses of Fluarix at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.	
Reporting group title	GSK2604409A Group
Reporting group description:	
Subjects aged 3-17 years received if primed, 1 dose of GSK2604409A at Day 0 and if unprimed, 2 doses of GSK2604409A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.	
Reporting group title	GSK2321138A 2 Group
Reporting group description:	
Subjects aged 6-35 months received if primed, 1 dose of GSK2321138A at Day 0 and if unprimed, 2 doses of GSK2321138A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.	

Reporting group values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group
Number of subjects	915	912	911
Age categorical			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
Units: months			
geometric mean	98.5	98.2	99.6
standard deviation	± 44.4	± 45.5	± 44.2
Gender categorical			
Units: Subjects			
Female	443	439	440

Male	472	473	471
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Reporting group values	GSK2321138A 2 Group	Total	
Number of subjects	277	3015	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: months			
geometric mean	22.1		
standard deviation	± 8.02	-	
Gender categorical Units: Subjects			
Female	118	1440	
Male	159	1575	

End points

End points reporting groups

Reporting group title	GSK2321138A 1 Group
Reporting group description: Subjects aged 3-17 years received if primed, 1 dose of GSK2321138A at Day 0 and if unprimed, 2 doses of GSK2321138A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.	
Reporting group title	Fluarix Group
Reporting group description: Subjects aged 3-17 years received if primed, 1 dose of Fluarix at Day 0 and if unprimed, 2 doses of Fluarix at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.	
Reporting group title	GSK2604409A Group
Reporting group description: Subjects aged 3-17 years received if primed, 1 dose of GSK2604409A at Day 0 and if unprimed, 2 doses of GSK2604409A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.	
Reporting group title	GSK2321138A 2 Group
Reporting group description: Subjects aged 6-35 months received if primed, 1 dose of GSK2321138A at Day 0 and if unprimed, 2 doses of GSK2321138A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.	

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. ^[1]
End point description: Titers are presented as geometric mean titers (GMTs). The reference cut-off value was 1:10. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata).	
End point type	Primary
End point timeframe: At Day 0 [PRE] and at Day 28 (for primed subjects) and 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	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	791	819	801	234
Units: Titers				
geometric mean (confidence interval 95%)				
FLU A/Cal/7/09, PRE [N=790;819;800;232]	21.6 (19.7 to 23.7)	24.9 (22.8 to 27.3)	22.1 (20.1 to 24.2)	12.3 (10.2 to 14.8)
FLU A/Cal/7/09, POST [N=791;818;801;234]	386.2 (357.3 to 417.4)	433.2 (401 to 468)	422.3 (390.5 to 456.5)	140 (113.7 to 172.3)
FLU A/Vic/210/09, PRE [N=790;819;800;232]	29 (26.6 to 31.6)	31.4 (28.8 to 34.2)	31.2 (28.6 to 34.2)	8.6 (7.4 to 9.9)
FLU A/Vic/210/09, POST [N=791;818;801;234]	228.8 (215 to 243.4)	227.3 (213.3 to 242.3)	234 (219.1 to 249.9)	87.5 (73.8 to 103.7)
FLU B/Bri/60/08, PRE [N=790;819;800;232]	30.9 (28.2 to 33.9)	31 (28.2 to 34)	33.2 (30.2 to 36.6)	9 (7.9 to 10.4)
FLU B/Bri/60/08, POST [N=791;818;801;234]	244.2 (227.5 to 262.1)	245.6 (229.2 to 263.2)	88.4 (81.5 to 95.8)	86.4 (72.6 to 102.9)
FLU B/Bri/3/07, PRE [N=790;819;800;232]	77.3 (70 to 85.3)	77.2 (70 to 85.2)	84.7 (76.6 to 93.6)	13.1 (11.4 to 15.2)
FLU B/Bri/3/07, POST [N=791;818;801;234]	569.6 (533.6 to 608.1)	224.7 (207.9 to 242.9)	643.3 (603.2 to 686.1)	167.7 (144.1 to 195.3)

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroconverted subjects against 4 strains of influenza disease. ^[2]
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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 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07

End point type	Primary
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End point timeframe:

At Day 28 (for primed subjects) and Day 56 (for unprimed subjects)

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

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	790	818	800	232
Units: Subjects				
FLU A/California/7/09	722	735	733	181
FLU A/Victoria/210/09	571	578	575	159
FLU B/Brisbane/60/08	553	560	237	158
FLU B/Brisbane/3/07	573	303	566	191

Statistical analyses

No statistical analyses for this end point

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

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease by age strata. ^[3]
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End point description:

Titers are presented as geometric mean titers (GMTs). The reference cut-off value was 1:10. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 3-8 years and 9-17 years.

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and 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: Subjects were assessed according to 2 age strata (3-8 years and 9-17 years) in the GSK2321138A 1 Group, the Fluarix Group and the GSK2604409A Group.

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	791	819	801	
Units: Titers				
geometric mean (confidence interval 95%)				
FLU A/Cal/7/09, PRE, 3-8 years [N=488;511;503]	20.7 (18.3 to 23.3)	22.2 (19.8 to 24.9)	22.4 (19.8 to 25.3)	
FLU A/Cal/7/09, POST, 3-8 years [N=489;510;504]	353.4 (319.9 to 390.3)	382.1 (345.4 to 422.7)	381.3 (345 to 421.5)	
FLU A/Cal/7/09, PRE, 9-17 years [N=302;308;297]	23.2 (20.2 to 26.6)	30.2 (26.1 to 34.9)	21.5 (18.6 to 24.8)	
FLU A/Cal/7/09, POST, 9-17 years [N=302;308;297]	445.8 (393.9 to 504.7)	533.3 (474.9 to 599)	502 (444.1 to 567.5)	
FLU A/Vic/210/09, PRE, 3-8 years [N=488;511;503]	29.3 (26.1 to 32.9)	32.9 (29.2 to 37)	31.5 (28 to 35.5)	
FLU A/Vic/210/09, POST, 3-8 years [N=489;510;504]	245.5 (226.4 to 266.2)	242 (222.9 to 262.8)	244.4 (224.1 to 266.5)	
FLU A/Vic/210/09, PRE, 9-17 years [N=302;308;297]	28.5 (25.1 to 32.3)	29 (25.8 to 32.7)	30.8 (27 to 35.1)	
FLU A/Vic/210/09, POST, 9-17 years [N=302;308;297]	204.1 (185.5 to 224.5)	204.9 (185.4 to 226.6)	217.5 (196.9 to 240.2)	
FLU B/Bri/60/08, PRE, 3-8 years [N=488;511;503]	27.1 (24 to 30.6)	25.1 (22.3 to 28.3)	27.9 (24.6 to 31.6)	
FLU B/Bri/60/08, POST, 3-8 years [N=489;510;504]	236.3 (215.4 to 259.2)	222.3 (202.8 to 243.7)	79.2 (71.2 to 88.2)	
FLU B/Bri/60/08, PRE, 9-17 years [N=302;308;297]	38.3 (33.4 to 43.9)	43.9 (38.2 to 50.6)	44.7 (38.6 to 51.7)	

FLU B/Bri/60/08, POST, 9-17 years [N=302;308;297]	257.5 (230.7 to 287.5)	289.8 (262.1 to 320.4)	106.4 (94.6 to 119.8)	
FLU B/Bri/3/07, PRE, 3-8 years [N=488;511;503]	54.9 (48.7 to 61.9)	51.9 (45.9 to 58.7)	57.6 (50.9 to 65.1)	
FLU B/Bri/3/07, POST, 3-8 years [N=489;510;504]	481.3 (443.2 to 522.8)	163.5 (148.4 to 180.1)	566.7 (522.9 to 614.1)	
FLU B/Bri/3/07, PRE, 9-17 years [N=302;308;297]	134.3 (115.2 to 156.5)	149.3 (130.3 to 171.1)	162.8 (140.4 to 188.6)	
FLU B/Bri/3/07, POST, 9-17 years [N=302;308;297]	748.1 (676.9 to 826.8)	380.6 (342.1 to 423.4)	797.9 (719.5 to 885)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease by age strata. ^[4]
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End point description:

Titers are presented as geometric mean titers (GMTs). The reference cut-off value was 1:10. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 6-17 months and 18-35 months.

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

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: Subjects were assessed according to 2 age strata (6-17 months and 18-35 months) in the GSK2321138A 2 Group.

End point values	GSK2321138A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	234			
Units: Titers				
geometric mean (confidence interval 95%)				
FLU A/Cal/7/09, PRE, 6-17 months [N=70]	7.1 (5.5 to 9.1)			
FLU A/Cal/7/09, POST, 6-17 months [N=71]	56.2 (39.9 to 79.2)			
FLU A/Cal/7/09, PRE, 18-35 months [N=162]	15.6 (12.3 to 19.8)			
FLU A/Cal/7/09, POST, 18-35 months [N=163]	208.3 (164.6 to 263.4)			
FLU A/Vic/210/09, PRE, 6-17 months [N=70]	6.2 (5.1 to 7.6)			
FLU A/Vic/210/09, POST, 6-17 months [N=71]	43.8 (33.7 to 57)			
FLU A/Vic/210/09, PRE, 18-35 months [N=162]	9.8 (8.1 to 11.9)			
FLU A/Vic/210/09, POST, 18-35 months [N=163]	118.2 (96.8 to 144.4)			

FLU B/Bri/60/08, PRE, 6-17 months [N=70]	5.9 (5.3 to 6.6)			
FLU B/Bri/60/08, POST, 6-17 months [N=71]	40.2 (31.2 to 51.6)			
FLU B/Bri/60/08, PRE, 18-35 months [N=162]	10.8 (9 to 13.1)			
FLU B/Bri/60/08, POST, 18-35 months [N=163]	120.7 (98.2 to 148.4)			
FLU B/Bri/3/07, PRE, 6-17 months [N=70]	10 (7.9 to 12.7)			
FLU B/Bri/3/07, POST, 6-17 months [N=71]	93.5 (73.5 to 119)			
FLU B/Bri/3/07, PRE, 18-35 months [N=162]	14.8 (12.4 to 17.7)			
FLU B/Bri/3/07, POST, 18-35 months [N=163]	216.3 (180.9 to 258.7)			

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroconverted subjects against 4 strains of influenza disease by age strata. ^[5]
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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 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 3-8 years and 9-17 years.

End point type	Secondary
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End point timeframe:

At Day 28 (for primed subjects) and Day 56 (for unprimed subjects)

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: Subjects were assessed according to 2 age strata (3-8 years and 9-17 years) in the GSK2321138A 1 Group, the Fluarix Group and the GSK2604409A Group.

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	790	818	800	
Units: Subjects				
FLU A/California/7/09, 3-8 years [N=488;510;503]	447	468	457	
FLU A/California/7/09, 9-17 years [N=302;308;297]	275	267	276	
FLU A/Victoria/210/09, 3-8 years [N=488;510;503]	367	365	376	
FLU A/Victoria/210/09, 9-17 years [N=302;308;297]	204	213	199	
FLU B/Brisbane/60/08, 3-8 years [N=488;510;503]	364	367	154	
FLU B/Brisbane/60/08, 9-17 years [N=302;308;297]	189	193	83	

FLU B/Brisbane/3/07, 3-8 years [N=488;510;503]	376	203	403	
FLU B/Brisbane/3/07, 9-17 years [N=302;308;297]	197	100	163	

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroconverted subjects against 4 strains of influenza disease by age strata. ^[6]
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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 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 6-17 months and 18-35 months.

End point type	Secondary
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End point timeframe:

At Day 28 (for primed subjects) and Day 56 (for unprimed subjects)

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: Subjects were assessed according to 2 age strata (6-17 months and 18-35 months) in the GSK2321138A 2 Group.

End point values	GSK2321138A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	232			
Units: Subjects				
FLU A/California/7/09, 6-17 months [N=70]	43			
FLU A/California/7/09, 18-35 months [N=162]	138			
FLU A/Victoria/210/09, 6-17 months [N=70]	37			
FLU A/Victoria/210/09, 18-35 months [N=162]	122			
FLU B/Brisbane/60/08, 6-17 months [N=70]	36			
FLU B/Brisbane/60/08, 18-35 months [N=162]	122			
FLU B/Brisbane/3/07, 6-17 months [N=70]	52			
FLU B/Brisbane/3/07, 18-35 months [N=162]	139			

Statistical analyses

No statistical analyses for this end point

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

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

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:40$. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata).

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	791	819	801	234
Units: Subjects				
FLU A/California/7/09, PRE [N=790;819;800;232]	343	404	353	60
FLU A/California/7/09, POST [N=791;818;801;234]	764	793	778	187
FLU A/Victoria/210/09, PRE [N=790;819;800;232]	381	412	409	34
FLU A/Victoria/210/09, POST [N=791;818;801;234]	775	800	773	169
FLU B/Brisbane/60/08, PRE [N=790;819;800;232]	381	396	399	28
FLU B/Brisbane/60/08, POST [N=791;818;801;234]	770	790	639	167
FLU B/Brisbane/3/07, PRE [N=790;819;800;232]	565	575	593	48
FLU B/Brisbane/3/07, POST [N=791;818;801;234]	785	772	798	212

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroprotected subjects against 4 strains of influenza disease by age strata. ^[7]
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End point description:

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:40$. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 3-8 years and 9-17 years.

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and 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: Subjects were assessed according to 2 age strata (3-8 years and 9-17 years) in the GSK2321138A 1 Group, the Fluarix Group and the GSK2604409A Group.

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	791	819	801	
Units: Subjects				
FLU A/Cal/7/09, PRE, 3-8 years [N=488;511;503]	206	234	230	
FLU A/Cal/7/09, POST, 3-8 years [N=489;510;504]	469	491	487	
FLU A/Cal/7/09, PRE, 9-17 years [N=302;308;297]	137	170	123	
FLU A/Cal/7/09, POST, 9-17 years [N=302;308;297]	295	302	291	
FLU A/Vic/210/09, PRE, 3-8 years [N=488;511;503]	253	277	269	
FLU A/Vic/210/09, POST, 3-8 years [N=489;510;504]	477	496	481	
FLU A/Vic/210/09, PRE, 9-17 years [N=302;308;297]	128	135	140	
FLU A/Vic/210/09, POST, 9-17 years [N=302;308;297]	298	304	292	
FLU B/Bri/60/08, PRE, 3-8 years [N=488;511;503]	217	218	232	
FLU B/Bri/60/08, POST, 3-8 years [N=489;510;504]	478	489	378	
FLU B/Bri/60/08, PRE, 9-17 years [N=302;308;297]	164	178	167	
FLU B/Bri/60/08, POST, 9-17 years [N=302;308;297]	292	301	261	
FLU B/Bri/3/07, PRE, 3-8 years [N=488;511;503]	315	309	329	
FLU B/Bri/3/07, POST, 3-8 years [N=489;510;504]	485	465	503	
FLU B/Bri/3/07, PRE, 9-17 years [N=302;308;297]	250	266	264	
FLU B/Bri/3/07, POST, 9-17 years [N=302;308;297]	300	307	295	

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroprotected subjects against 4 strains of influenza disease by age strata. ^[8]
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End point description:

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:40$. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 6-17 months and 18-35 months.

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

Notes:

[8] - 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: Subjects were assessed according to 2 age strata (6-17 months and 18-35 months) in the GSK2321138A 2 Group.

End point values	GSK2321138A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	234			
Units: Subjects				
FLU A/Cal/7/09, PRE, 6-17 months [N=70]	6			
FLU A/Cal/7/09, POST, 6-17 months [N=71]	45			
FLU A/Cal/7/09, PRE, 18-35 months [N=162]	54			
FLU A/Cal/7/09, POST, 18-35 months [N=163]	142			
FLU A/Vic/210/09, PRE, 6-17 months [N=70]	4			
FLU A/Vic/210/09, POST, 6-17 months [N=71]	39			
FLU A/Vic/210/09, PRE, 18-35 months [N=162]	30			
FLU A/Vic/210/09, POST, 18-35 months [N=163]	130			
FLU B/Bri/60/08, PRE, 6-17 months [N=70]	1			
FLU B/Bri/60/08, POST, 6-17 months [N=71]	38			
FLU B/Bri/60/08, PRE, 18-35 months [N=162]	27			
FLU B/Bri/60/08, POST, 18-35 months [N=163]	129			
FLU B/Bri/3/07, PRE, 6-17 months [N=70]	11			
FLU B/Bri/3/07, POST, 6-17 months [N=71]	61			
FLU B/Bri/3/07, PRE, 18-35 months [N=162]	37			
FLU B/Bri/3/07, POST, 18-35 months [N=163]	151			

Statistical analyses

No statistical analyses for this end point

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

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

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:80$. The 4

influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata).

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	791	819	801	234
Units: Subjects				
FLU A/California/7/09, PRE [N=790;819;800;232]	201	218	202	49
FLU A/California/7/09, POST [N=791;818;801;234]	732	763	744	155
FLU A/Victoria/210/09, PRE [N=790;819;800;232]	228	245	267	27
FLU A/Victoria/210/09, POST [N=791;818;801;234]	721	748	721	125
FLU B/Brisbane/60/08, PRE [N=790;819;800;232]	244	258	269	18
FLU B/Brisbane/60/08, POST [N=791;818;801;234]	708	733	488	140
FLU B/Brisbane/3/07, PRE [N=790;819;800;232]	454	462	476	24
FLU B/Brisbane/3/07, POST [N=791;818;801;234]	779	692	784	175

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroprotected subjects against 4 strains of influenza disease by age strata. ^[9]
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End point description:

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:80$. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 3-8 years and 9-17 years.

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

Notes:

[9] - 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: Subjects were assessed according to 2 age strata (3-8 years and 9-17 years) in the GSK2321138A 1 Group, the Fluarix Group and the GSK2604409A Group.

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	791	819	801	
Units: Subjects				
FLU A/Cal/7/09, PRE, 3-8 years [N=488;511;503]	130	128	141	
FLU A/Cal/7/09, POST, 3-8 years [N=489;510;504]	453	471	464	
FLU A/Cal/7/09, PRE, 9-17 years [N=302;308;297]	71	90	61	
FLU A/Cal/7/09, POST, 9-17 years [N=302;308;297]	279	292	280	
FLU A/Vic/210/09, PRE, 3-8 years [N=488; 511;503]	156	177	190	
FLU A/Vic/210/09, POST, 3-8 years [N=489; 510;504]	446	462	446	
FLU A/Vic/210/09, PRE, 9-17 years [N=302;308;297]	72	68	77	
FLU A/Vic/210/09, POST, 9-17 years [N=302;308;297]	275	286	275	
FLU B/Bri/60/08, PRE, 3-8 years [N=488;511;503]	145	140	150	
FLU B/Bri/60/08, POST, 3-8 years [N=489;510;504]	430	441	286	
FLU B/Bri/60/08, PRE, 9-17 years [N=302;308;297]	99	118	119	
FLU B/Bri/60/08, POST, 9-17 years [N=302;308;297]	278	292	202	
FLU B/Bri/3/07, PRE, 3-8 years [N=488;511;503]	233	227	248	
FLU B/Bri/3/07, POST, 3-8 years [N=489;510;504]	480	395	493	
FLU B/Bri/3/07, PRE, 9-17 years [N=302;308;297]	221	235	228	
FLU B/Bri/3/07, POST, 9-17 years [N=302;308;297]	299	297	291	

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroprotected subjects against 4 strains of influenza disease by age strata. ^[10]
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End point description:

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:80$. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 6-17 months and 18-35 months.

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

Notes:

[10] - 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: Subjects were assessed according to 2 age strata (6 -17 months and 18-35 months) in the GSK2321138A 2 Group.

End point values	GSK2321138A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	234			
Units: Subjects				
FLU A/California/7/09, PRE, 6-17 months [N=70]	6			
FLU A/California/7/09, POST, 6-17 months [N=71]	31			
FLU A/California/7/09, PRE, 18-35 months [N=162]	43			
FLU A/California/7/09, POST, 18-35 months [N=163]	124			
FLU A/Victoria/210/09, PRE, 6-17 months [N=70]	4			
FLU A/Victoria/210/09, POST, 6-17 months [N=71]	18			
FLU A/Victoria/210/09, PRE, 18-35 months [N=162]	23			
FLU A/Victoria/210/09, POST, 18-35 months [N=163]	107			
FLU B/Brisbane/60/08, PRE, 6-17 months [N=70]	0			
FLU B/Brisbane/60/08, POST, 6-17 months [N=71]	25			
FLU B/Brisbane/60/08, PRE, 18-35 months [N=162]	18			
FLU B/Brisbane/60/08, POST, 18-35 months [N=163]	115			
FLU B/Brisbane/3/07, PRE, 6-17 months [N=70]	4			
FLU B/Brisbane/3/07, POST, 6-17 months [N=71]	43			
FLU B/Brisbane/3/07, PRE, 18-35 months [N=162]	20			
FLU B/Brisbane/3/07, POST, 18-35 months [N=163]	132			

Statistical analyses

No statistical analyses for this end point

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

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

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:120$. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata).

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	791	819	801	234
Units: Subjects				
FLU A/California/7/09, PRE [N=790;819;800;232]	71	92	79	28
FLU A/California/7/09, POST [N=791;818;801;234]	669	720	690	122
FLU A/Victoria/210/09, PRE [N=790;819;800;232]	103	124	121	15
FLU A/Victoria/210/09, POST [N=791;818;801;234]	597	597	599	82
FLU B/Brisbane/60/08, PRE [N=790;819;800;232]	123	126	148	9
FLU B/Brisbane/60/08, POST [N=791;818;801;234]	578	607	300	83
FLU B/Brisbane/3/07, PRE [N=790;819;800;232]	300	324	327	7
FLU B/Brisbane/3/07, POST [N=791;818;801;234]	730	564	756	129

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroprotected subjects against 4 strains of influenza disease by age strata. ^[11]
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End point description:

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:120$. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 3-8 years and 9-17 years.

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

Notes:

[11] - 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: Subjects were assessed according to 2 age strata (3-8 years and 9-17 years) in the GSK2321138A 1 Group, the Fluarix Group and the GSK2604409A Group.

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	791	819	801	
Units: Subjects				
FLU A/Cal/7/09, PRE, 3-8 years [N=488;511;503]	47	56	57	
FLU A/Cal/7/09, POST, 3-8 years [N=489;510;504]	410	442	428	
FLU A/Cal/7/09, PRE, 9-17 years [N=302;308;297]	24	36	22	
FLU A/Cal/7/09, POST, 9-17 years [N=302;308;297]	259	278	262	
FLU A/Vic/210/09, PRE, 3-8 years [N=488;511;503]	70	92	87	
FLU A/Vic/210/09, POST, 3-8 years [N=489;510;504]	380	385	390	
FLU A/Vic/210/09, PRE, 9-17 years [N=302;308;297]	33	32	34	
FLU A/Vic/210/09, POST, 9-17 years [N=302;308;297]	271	212	209	
FLU B/Bri/60/08, PRE, 3-8 years [N=488;511;503]	75	66	82	
FLU B/Bri/60/08, POST, 3-8 years [N=489;510;504]	349	357	174	
FLU B/Bri/60/08, PRE, 9-17 years [N=302;308;297]	48	60	66	
FLU B/Bri/60/08, POST, 9-17 years [N=302;308;297]	229	250	126	
FLU B/Bri/3/07, PRE, 3-8 years [N=488;511;503]	135	155	150	
FLU B/Bri/3/07, POST, 3-8 years [N=489;510;504]	444	301	473	
FLU B/Bri/3/07, PRE, 9-17 years [N=302;308;297]	165	169	177	
FLU B/Bri/3/07, POST, 9-17 years [N=302;308;297]	286	263	283	

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of seroprotected subjects against 4 strains of influenza disease by age strata. ^[12]
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End point description:

A seroprotected subject was defined as a vaccinated subject who had a serum HI titer $\geq 1:120$. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 6 -17 months and 18-35 months.

End point type	Secondary
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End point timeframe:

At Day 0 [PRE] and at Day 28 (for primed subjects) and Day 56 (for unprimed subjects) [POST]

Notes:

[12] - 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: Subjects were assessed according to 2 age strata (6-17 months and 18-35 months) in the GSK2321138A 2 Group.

End point values	GSK2321138A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	234			
Units: Subjects				
FLU A/California/7/09, PRE, 6-17 months [N=70]	5			
FLU A/California/7/09, POST, 6-17 months [N=71]	18			
FLU A/California/7/09, PRE, 18-35 months [N=162]	23			
FLU A/California/7/09, POST, 18-35 months [N=163]	104			
FLU A/Victoria/210/09, PRE, 6-17 months [N=70]	3			
FLU A/Victoria/210/09, POST, 6-17 months [N=71]	11			
FLU A/Victoria/210/09, PRE, 18-35 months [N=162]	12			
FLU A/Victoria/210/09, POST, 18-35 months [N=163]	71			
FLU B/Brisbane/60/08, PRE, 6-17 months [N=70]	0			
FLU B/Brisbane/60/08, POST, 6-17 months [N=71]	7			
FLU B/Brisbane/60/08, PRE, 18-35 months [N=162]	9			
FLU B/Brisbane/60/08, POST, 18-35 months [N=163]	76			
FLU B/Brisbane/3/07, PRE, 6-17 months [N=70]	1			
FLU B/Brisbane/3/07, POST, 6-17 months [N=71]	25			
FLU B/Brisbane/3/07, PRE, 18-35 months [N=162]	6			
FLU B/Brisbane/3/07, POST, 18-35 months [N=163]	104			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Geometric Increase (MGI) titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease.

End point title	Mean Geometric Increase (MGI) titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease.
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End point description:

MGI is defined as the geometric mean of the within subject ratios of the post-vaccination reciprocal HI titer to the Day 0 reciprocal HI titer. The 4 influenza strains assessed were the FLU A/California/7/09

(H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata).

End point type	Secondary
End point timeframe:	
At Day 28 (for primed subjects) and Day 56 (for unprimed subjects)	

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	790	818	800	232
Units: fold increase				
geometric mean (confidence interval 95%)				
FLU A/California/7/09	18 (16.6 to 19.5)	17.4 (16 to 18.8)	19.2 (17.7 to 20.9)	11.7 (10.2 to 13.4)
FLU A/Victoria/210/09	7.9 (7.3 to 8.6)	7.2 (6.7 to 7.8)	7.5 (6.9 to 8.1)	10.4 (9 to 11.9)
FLU B/Brisbane/60/08	7.9 (7.3 to 8.6)	7.9 (7.2 to 8.6)	2.7 (2.5 to 2.9)	9.7 (8.5 to 11.2)
FLU B/Brisbane/3/07	7.4 (6.8 to 8)	2.9 (2.7 to 3.1)	7.6 (7 to 8.3)	12.9 (11 to 15.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Geometric Increase (MGI) titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease by age strata.

End point title	Mean Geometric Increase (MGI) titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease by age strata. ^[13]
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End point description:

MGI is defined as the geometric mean of the within subject ratios of the post-vaccination reciprocal HI titer to the Day 0 reciprocal HI titer. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 3-8 years and 9-17 years.

End point type	Secondary
End point timeframe:	
At Day 28 (for primed subjects) and Day 56 (for unprimed subjects)	

Notes:

[13] - 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: Subjects were assessed according to 2 age strata (3-8 years and 9-17 years) in the GSK2321138A 1 Group, the Fluarix Group and the GSK2604409A Group.

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	790	818	800	
Units: fold increase				
geometric mean (confidence interval 95%)				
FLU A/California/7/09, 3-8 years [N=488;510;503]	17.2 (15.6 to 19)	17.2 (15.6 to 18.9)	17.2 (15.6 to 18.9)	
FLU A/California/7/09, 9-17 years [N=302;308;297]	19.2 (16.7 to 22.2)	17.7 (15.2 to 20.5)	23.3 (20.3 to 26.9)	
FLU A/Victoria/210/09, 3-8 years [N=488;510;503]	8.4 (7.6 to 9.3)	7.3 (6.6 to 8.1)	7.8 (7.1 to 8.5)	
FLU A/Victoria/210/09, 9-17 years [N=302;308;297]	7.2 (6.2 to 8.2)	7.1 (6.2 to 8.1)	7.1 (6.2 to 8.1)	
FLU B/Brisbane/60/08, 3-8 years [N=488;510;503]	8.8 (7.9 to 9.8)	8.8 (7.9 to 9.8)	2.8 (2.6 to 3.1)	
FLU B/Brisbane/60/08, 9-17 years [N=302;308;297]	6.7 (5.8 to 7.8)	6.6 (5.7 to 7.6)	2.4 (2.1 to 2.7)	
FLU B/Brisbane/3/07, 3-8 years [N=488;510;503]	8.8 (7.9 to 9.8)	3.1 (2.9 to 3.4)	9.9 (8.9 to 11)	
FLU B/Brisbane/3/07, 9-17 years [N=302;308;297]	5.6 (4.9 to 6.3)	2.5 (2.3 to 2.8)	4.9 (4.3 to 5.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Geometric Increase (MGI) titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease by age strata.

End point title	Mean Geometric Increase (MGI) titers for serum Hemagglutination Inhibition (HI) antibodies against 4 strains of influenza disease by age strata. ^[14]
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End point description:

MGI is defined as the geometric mean of the within subject ratios of the post-vaccination reciprocal HI titer to the Day 0 reciprocal HI titer. The 4 influenza strains assessed were the FLU A/California/7/09 (H1N1), FLU A/Victoria/210/09 (H3N2), FLU B/Brisbane/60/08 (Victoria) and FLU B/Brisbane/3/07 (Yamagata). Subjects were assessed according to 2 age strata: 6 -17 months and 18-35 months.

End point type	Secondary
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End point timeframe:

At Day 28 (for primed subjects) and Day 56 (for unprimed subjects)

Notes:

[14] - 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: Subjects were assessed according to 2 age strata (6-17 months and 18-35 months) in the GSK2321138A 2 Group.

End point values	GSK2321138A 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	232			
Units: fold increase				
geometric mean (confidence interval 95%)				

FLU A/California/7/09, 6-17 months [N=70]	8.2 (6.4 to 10.6)			
FLU A/California/7/09, 18-35 months [N=162]	13.7 (11.7 to 16)			
FLU A/Victoria/210/09, 6-17 months [N=70]	7.3 (5.9 to 9)			
FLU A/Victoria/210/09, 18-35 months [N=162]	12.1 (10.2 to 14.3)			
FLU B/Brisbane/60/08, 6-17 months [N=70]	6.9 (5.4 to 8.9)			
FLU B/Brisbane/60/08, 18-35 months [N=162]	11.3 (9.6 to 13.2)			
FLU B/Brisbane/3/07, 6-17 months [N=70]	9.5 (7 to 12.8)			
FLU B/Brisbane/3/07, 18-35 months [N=162]	14.8 (12.2 to 18)			

Statistical analyses

No statistical analyses for this end point

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

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

Assessed solicited local symptoms were pain, redness and swelling at the injection site. Any = incidence of a particular symptom regardless of intensity grade. Grade 3 pain = Cried when limb was moved/spontaneously painful (Child <6 years) or pain that prevented normal activity (Child >6 years). Grade 3 redness/swelling = redness/swelling spreading beyond 50 millimeters (mm) of the injection site.

End point type	Secondary
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End point timeframe:

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

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	903	902	906	277
Units: Subjects				
Any Pain	444	425	416	116
Grade 3 Pain	20	21	13	5
Any Redness	225	214	206	100
Grade 3 Redness	12	3	6	1
Any Swelling	196	193	160	67
Grade 3 Swelling	11	10	3	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms in subjects younger than 6 years old.

End point title	Number of subjects with any, grade 3 and related solicited general symptoms in subjects younger than 6 years old.
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End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and temperature [axillary temperature equal to or above 37.5 degrees Celsius (°C)]. Any = occurrence of any solicited general symptom regardless of intensity grade or relation to vaccination. Grade 3 drowsiness = drowsiness that prevented normal activity. Grade 3 irritability = crying that could not be comforted/prevented normal activity. Grade 3 loss of appetite = not eating at all. Related = general symptom assessed by the investigator as causally related to the study vaccination. Grade 3 temperature = temperature >39.0°C.

End point type	Secondary
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End point timeframe:

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

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	291	314	280	277
Units: Subjects				
Any Drowsiness	67	55	59	84
Grade 3 Drowsiness	5	3	2	7
Related Drowsiness	44	31	36	57
Any Irritability	65	56	53	119
Grade 3 Irritability	4	2	3	11
Related Irritability	44	37	31	81
Any Loss of appetite	59	40	47	83
Grade 3 Loss of appetite	3	3	3	12
Related Loss of appetite	37	24	25	50
Temperature ≥37.5°C	50	51	41	81
Temperature >39°C	4	2	3	18
Related Temperature	24	29	16	37

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms in subjects aged 6 years or older.

End point title	Number of subjects with any, grade 3 and related solicited general symptoms in subjects aged 6 years or older. ^[15]
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End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and temperature [axillary temperature equal to or above 37.5 degrees Celsius (°C)]. Any = occurrence of any solicited general symptom regardless of intensity grade or relation to vaccination. Grade 3 drowsiness = drowsiness that prevented normal activity. Grade 3 irritability = crying that could not be comforted/prevented normal activity. Grade 3 loss of appetite = not eating at all. Related = general

symptom assessed by the investigator as causally related to the study vaccination. Grade 3 temperature = temperature >39.0°C.

End point type	Secondary
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End point timeframe:

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

Notes:

[15] - 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: Only the following groups had subjects aged 6 years or older: GSK2321138A 1 Group, Fluarix Group and GSK2604409A Group.

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	613	589	626	
Units: Subjects				
Any Fatigue	129	118	114	
Grade 3 Fatigue	9	8	4	
Related Fatigue	95	81	76	
Any Gastro.	66	62	52	
Grade 3 Gastro.	7	4	2	
Related Gastro.	31	29	26	
Any Headache	110	125	114	
Grade 3 Headache	8	4	5	
Related Headache	66	75	71	
Any Joint Pain	69	63	51	
Grade 3 Joint Pain	2	4	2	
Related Joint Pain	44	43	36	
Any Muscle aches	116	106	106	
Grade 3 Muscle aches	4	8	3	
Related Muscle aches	84	81	87	
Any Shivering	44	31	37	
Grade 3 Shivering	3	3	1	
Related Shivering	27	23	22	
Temperature ≥37.5°C	48	60	47	
Temperature >39°C	7	5	3	
Related Temperature	25	30	32	

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 = any unsolicited AE regardless of intensity or relationship to vaccination. Grade 3 = unsolicited AE that prevented normal activity Related = unsolicited AE assessed by the investigator as related to the

vaccination.

End point type	Secondary
End point timeframe:	
During the 28-day (Days 0-27) follow-up period after any vaccination.	

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	915	912	911	277
Units: Subjects				
Subjects with any AE(s)	284	305	308	167
Subjects with grade 3 AE(s)	20	37	26	20
Subjects with related AE(s)	18	19	23	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related medically attended adverse events (MAEs).

End point title	Number of subjects with any, grade 3 and related medically attended adverse events (MAEs).
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End point description:

MAEs were defined as AEs that resulted in medical attention (defined as hospitalization, an emergency room visit or a visit to or from medical personnel for any reason). Any = any MAE regardless of intensity or relationship to vaccination. Grade 3 MAE = MAE which prevented normal, everyday activities. Related = MAE assessed by the investigator as related to the vaccination. Assessment of intensity for MAEs was not performed.

End point type	Secondary
End point timeframe:	
During the entire study period (Day 0 - Day 180)	

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	915 ^[16]	912 ^[17]	911 ^[18]	277 ^[19]
Units: Subjects				
Subjects with any MAE(s)	271	278	303	171
Subjects with related MAE(s)	2	4	4	2
Subjects with Grade 3 MAE(s)	0	0	0	0

Notes:

[16] - Analyses was not performed for Grade 3 MAEs as done in the FDAAA record.

[17] - Analyses was not performed for Grade 3 MAEs as done in the FDAAA record.

[18] - Analyses was not performed for Grade 3 MAEs as done in the FDAAA record.

[19] - Analyses was not performed for Grade 3 MAEs as done in the FDAAA record.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and related Potential Immune-Mediated Diseases (pIMDs).

End point title	Number of subjects with any and related Potential Immune-Mediated Diseases (pIMDs).
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End point description:

pIMDs were defined as a subset of AEs that included both clearly autoimmune diseases (AID) and also other inflammatory and/or neurologic disorders which may or may not have an autoimmune etiology.

End point type	Secondary
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End point timeframe:

During the entire study period (Day 0 - Day 180)

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	915	912	911	277
Units: Subjects				
Subjects with any pIMD(s)	0	0	2	0
Subjects with related pIMD(s)	0	0	0	0

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:

Serious adverse events (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.

End point type	Secondary
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End point timeframe:

During the entire study period (Day 0 - Day 180)

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	915	912	911	277
Units: Subjects				
Subjects with any SAE(s)	8	6	7	9
Subjects with related SAE(s)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of days with solicited local symptoms.

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

The number of days with any grade of local symptoms after Dose 1 and Dose 2 vaccination respectively was tabulated. Assessed solicited local symptoms for duration were pain, redness and swelling at the injection site.

End point type	Secondary
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End point timeframe:

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

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	395	382	365	94
Units: days				
median (inter-quartile range (Q1-Q3))				
Pain, Dose 1 [N=395;382;365;94]	2 (1 to 2)	2 (1 to 3)	2 (1 to 3)	1 (1 to 2)
Pain, Dose 2 [N=175;156;160;70]	2 (1 to 2)	2 (1 to 2)	2 (1 to 2)	2 (1 to 2)
Redness, Dose 1 [N=208;192;189;84]	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	2 (1.5 to 4)
Redness, Dose 2 [N=75;80;76;69]	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)
Swelling, Dose 1 [N=167;155;135;44]	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)
Swelling, Dose 2 [N=70;65;59;39]	2 (1 to 2)	2 (1 to 3)	2 (1 to 3)	2 (1 to 4)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of days with solicited general symptoms

End point title	Number of days with solicited general symptoms
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End point description:

The number of days with any grade of local symptoms after Dose 1 and Dose 2 vaccination respectively was tabulated. Assessed solicited general symptoms for duration were drowsiness, fatigue, gastrointestinal symptoms (Gastro.), headache, irritability, loss of appetite, muscle aches, shivering and temperature [axillary temperature equal to or above 37.5 degrees Celsius (°C)].

End point type	Secondary
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End point timeframe:

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

End point values	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group	GSK2321138A 2 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	121	113	97	79 ^[20]
Units: days				
median (inter-quartile range (Q1-Q3))				
Drowsiness, Dose 1 [N=50;39;38;66]	1 (1 to 2)	1 (1 to 2)	2 (1 to 3)	1 (1 to 3)
Drowsiness, Dose 2 [N=29;29;32;45]	2 (1 to 3)	1 (1 to 2)	1 (1 to 2)	2 (1 to 3)
Fatigue, Dose 1 [N=121;109;97;0]	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	0 (0 to 0)
Fatigue, Dose 2 [N=33;25;33;0]	1 (1 to 2)	2 (1 to 2)	1 (1 to 2)	0 (0 to 0)
Gastro., Dose 1 [N=60;56;45;0]	1 (1 to 2)	2 (1 to 2)	2 (1 to 2)	0 (0 to 0)
Gastro., Dose 2 [N=11;9;8;0]	1 (1 to 2)	2 (1 to 2)	1 (1 to 2)	0 (0 to 0)
Headache, Dose 1 [N=100;113;95;0]	1 (1 to 2.5)	1 (1 to 2)	1 (1 to 2)	0 (0 to 0)
Headache, Dose 2 [N=19;21;29;0]	1 (1 to 2)	1 (1 to 2)	1 (1 to 2)	0 (0 to 0)
Irritability, Dose 1 [N=49;42;40;79]	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)
Irritability, Dose 2 [N=37;33;27;79]	2 (1 to 3)	1 (1 to 3)	2 (1 to 3)	2 (1 to 3)
Joint pain, Dose 1 [N=60;55;46;0]	2 (1 to 3)	2 (1 to 3)	2 (1 to 2)	0 (0 to 0)
Joint pain, Dose 2 [N=18;14;10;0]	1 (1 to 2)	1 (1 to 2)	1.5 (1 to 2)	0 (0 to 0)
Loss of appetite, Dose 1 [N=45;29;25;56]	1 (1 to 4)	2 (1 to 3)	2 (1 to 4)	3 (1 to 4.5)
Loss of appetite, Dose 2 [N=22;26;26;50]	3 (1 to 4)	1 (1 to 3)	2 (1 to 2)	3 (2 to 4)
Muscle aches, Dose 1 [N=107;94;99;0]	2 (1 to 3)	2 (1 to 2)	2 (1 to 2)	0 (0 to 0)
Muscle aches, Dose 2 [N=25;20;19;0]	2 (1 to 3)	2 (1 to 2)	2 (1 to 2)	0 (0 to 0)
Shivering, Dose 1 [N=39;26;31;0]	1 (1 to 2)	2 (1 to 5)	1 (1 to 2)	0 (0 to 0)
Shivering, Dose 2 [N=7;6;7;0]	1 (1 to 3)	1.5 (1 to 3)	2 (1 to 2)	0 (0 to 0)
Temperature, Dose 1 [N=63;78;61;45]	1 (1 to 2)	1.5 (1 to 3)	2 (1 to 3)	1 (1 to 2)
Temperature, Dose 2 [N=40;44;33;53]	1.5 (1 to 2)	1.5 (1 to 2)	2 (1 to 3)	2 (1 to 3)

Notes:

[20] - Symptom not assessed in this group.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAE(s): during the entire study period (Day 0 - Day 180); Solicited local and general symptoms: during the 7-day (Days 0-6) follow-up period after any vaccination, Unsolicited AE(s): during the 28-day follow-up period (Days 0 to 27) after any vaccination.

Adverse event reporting additional description:

No reported SAE was assessed as related to study vaccination. For systematically assessed other AEs, the number of participants at risk included those from Total Vaccinated cohort with symptom sheet 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	GSK2321138A 1 Group
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Reporting group description:

Subjects aged 3-17 years received if primed, 1 dose of GSK2321138A at Day 0 and if unprimed, 2 doses of GSK2321138A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.

Reporting group title	Fluarix Group
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Reporting group description:

Subjects aged 3-17 years received if primed, 1 dose of Fluarix at Day 0 and if unprimed, 2 doses of Fluarix at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.

Reporting group title	GSK2604409A Group
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Reporting group description:

Subjects aged 3-17 years received if primed, 1 dose of GSK2604409A at Day 0 and if unprimed, 2 doses of GSK2604409A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.

Reporting group title	GSK2321138A 2 Group
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Reporting group description:

Subjects aged 6-35 months received if primed, 1 dose of GSK2321138A at Day 0 and if unprimed, 2 doses of GSK2321138A at Day 0 and Day 28. The vaccine was administered intramuscularly into the deltoid for subjects aged 12 months or above or into the anterolateral region of the thigh for subjects below 12 month of age. The vaccine was administered in the non-dominant side of the body at Day 0 and in the opposite side at Day 28.

Serious adverse events	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 915 (0.87%)	6 / 912 (0.66%)	7 / 911 (0.77%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0

Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 915 (0.00%)	1 / 912 (0.11%)	0 / 911 (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
Concussion			
subjects affected / exposed	3 / 915 (0.33%)	0 / 912 (0.00%)	2 / 911 (0.22%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 915 (0.00%)	1 / 912 (0.11%)	0 / 911 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	0 / 911 (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
Myocarditis			
subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	0 / 911 (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
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Febrile convulsion			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Blood and lymphatic system disorders			
Lymphadenitis			

subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	0 / 911 (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
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 915 (0.00%)	1 / 912 (0.11%)	1 / 911 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	1 / 911 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Amoebiasis			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Appendicitis			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	1 / 911 (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
Bronchiolitis			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Bronchitis			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Bronchopneumonia			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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

Dengue fever			
subjects affected / exposed	0 / 915 (0.00%)	2 / 912 (0.22%)	0 / 911 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Gastroenteritis bacterial			
subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	0 / 911 (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
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	1 / 911 (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 viral			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Infectious mononucleosis			
subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	0 / 911 (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
Otitis media acute			
subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	0 / 911 (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
Peritonsillar abscess			
subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	0 / 911 (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
Pneumococcal sepsis			

subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Pneumonia			
subjects affected / exposed	0 / 915 (0.00%)	2 / 912 (0.22%)	0 / 911 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	0 / 911 (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
Tonsillitis			
subjects affected / exposed	1 / 915 (0.11%)	0 / 912 (0.00%)	0 / 911 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	1 / 911 (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
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 915 (0.00%)	0 / 912 (0.00%)	1 / 911 (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	GSK2321138A 2 Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 277 (3.25%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Abdominal injury			

subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocarditis			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Epilepsy			
subjects affected / exposed	1 / 277 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion			
subjects affected / exposed	2 / 277 (0.72%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Skin and subcutaneous tissue disorders Rash			
	subjects affected / exposed	0 / 277 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Psychiatric disorders Suicidal ideation			
	subjects affected / exposed	0 / 277 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Infections and infestations Amoebiasis			
	subjects affected / exposed	1 / 277 (0.36%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
Appendicitis			
	subjects affected / exposed	0 / 277 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Bronchiolitis			
	subjects affected / exposed	1 / 277 (0.36%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
Bronchitis			
	subjects affected / exposed	3 / 277 (1.08%)	
	occurrences causally related to treatment / all	0 / 3	
	deaths causally related to treatment / all	0 / 0	
Bronchopneumonia			
	subjects affected / exposed	2 / 277 (0.72%)	
	occurrences causally related to treatment / all	0 / 2	
	deaths causally related to treatment / all	0 / 0	
Dengue fever			

subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	2 / 277 (0.72%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis bacterial			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	1 / 277 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious mononucleosis			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media acute			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumococcal sepsis			

subjects affected / exposed	1 / 277 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 277 (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	1 / 277 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	1 / 277 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 277 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 277 (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	GSK2321138A 1 Group	Fluarix Group	GSK2604409A Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	630 / 915 (68.85%)	616 / 912 (67.54%)	620 / 911 (68.06%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	23 / 915 (2.51%)	23 / 912 (2.52%)	28 / 911 (3.07%)
occurrences (all)	23	23	28

Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	129 / 613 (21.04%)	118 / 589 (20.03%)	114 / 626 (18.21%)
occurrences (all)	129	118	114
Gastrointestinal			
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	66 / 613 (10.77%)	62 / 589 (10.53%)	52 / 626 (8.31%)
occurrences (all)	66	62	52
Headache			
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	110 / 613 (17.94%)	125 / 589 (21.22%)	114 / 626 (18.21%)
occurrences (all)	110	125	114
Joint Pain			
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	69 / 613 (11.26%)	63 / 589 (10.70%)	51 / 626 (8.15%)
occurrences (all)	69	63	51
Muscle aches			
alternative assessment type: Systematic			
subjects affected / exposed ^[5]	116 / 613 (18.92%)	106 / 589 (18.00%)	106 / 626 (16.93%)
occurrences (all)	116	106	106
Temperature (Axillary) [subjects 6 years old or older]			
alternative assessment type: Systematic			
subjects affected / exposed ^[6]	48 / 613 (7.83%)	60 / 589 (10.19%)	47 / 626 (7.51%)
occurrences (all)	48	60	47
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed ^[7]	65 / 291 (22.34%)	56 / 314 (17.83%)	53 / 280 (18.93%)
occurrences (all)	65	56	53
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed ^[8]	67 / 291 (23.02%)	55 / 314 (17.52%)	59 / 280 (21.07%)
occurrences (all)	67	55	59
Loss of appetite			
alternative assessment type: Systematic			

subjects affected / exposed ^[9]	59 / 291 (20.27%)	40 / 314 (12.74%)	47 / 280 (16.79%)
occurrences (all)	59	40	47
Redness			
alternative assessment type: Systematic			
subjects affected / exposed ^[10]	225 / 903 (24.92%)	214 / 902 (23.73%)	206 / 906 (22.74%)
occurrences (all)	225	214	206
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed ^[11]	196 / 903 (21.71%)	193 / 902 (21.40%)	160 / 906 (17.66%)
occurrences (all)	196	193	160
Temperature (Axillary) [subjects younger than 6 years old]			
alternative assessment type: Systematic			
subjects affected / exposed ^[12]	50 / 291 (17.18%)	51 / 314 (16.24%)	41 / 280 (14.64%)
occurrences (all)	50	51	41
Shivering			
alternative assessment type: Systematic			
subjects affected / exposed ^[13]	44 / 613 (7.18%)	31 / 589 (5.26%)	37 / 626 (5.91%)
occurrences (all)	44	31	37
Pain			
alternative assessment type: Systematic			
subjects affected / exposed ^[14]	444 / 903 (49.17%)	425 / 902 (47.12%)	416 / 906 (45.92%)
occurrences (all)	444	425	416
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	40 / 915 (4.37%)	36 / 912 (3.95%)	45 / 911 (4.94%)
occurrences (all)	40	36	45
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	49 / 915 (5.36%)	60 / 912 (6.58%)	64 / 911 (7.03%)
occurrences (all)	49	60	64
Upper respiratory tract infection			
subjects affected / exposed	48 / 915 (5.25%)	51 / 912 (5.59%)	46 / 911 (5.05%)
occurrences (all)	48	51	46
Bronchitis			

subjects affected / exposed	13 / 915 (1.42%)	5 / 912 (0.55%)	12 / 911 (1.32%)
occurrences (all)	13	5	12

Non-serious adverse events	GSK2321138A 2 Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	237 / 277 (85.56%)		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	18 / 277 (6.50%)		
occurrences (all)	18		
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	0 / 277 (0.00%)		
occurrences (all)	0		
Gastrointestinal			
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	0 / 277 (0.00%)		
occurrences (all)	0		
Headache			
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	0 / 277 (0.00%)		
occurrences (all)	0		
Joint Pain			
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	0 / 277 (0.00%)		
occurrences (all)	0		
Muscle aches			
alternative assessment type: Systematic			
subjects affected / exposed ^[5]	0 / 277 (0.00%)		
occurrences (all)	0		
Temperature (Axillary) [subjects 6 years old or older]			
alternative assessment type: Systematic			
subjects affected / exposed ^[6]	0 / 277 (0.00%)		
occurrences (all)	0		

Irritability			
alternative assessment type: Systematic			
subjects affected / exposed ^[7]	119 / 277 (42.96%)		
occurrences (all)	119		
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed ^[8]	84 / 277 (30.32%)		
occurrences (all)	84		
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed ^[9]	83 / 277 (29.96%)		
occurrences (all)	83		
Redness			
alternative assessment type: Systematic			
subjects affected / exposed ^[10]	100 / 277 (36.10%)		
occurrences (all)	100		
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed ^[11]	67 / 277 (24.19%)		
occurrences (all)	67		
Temperature (Axillary) [subjects younger than 6 years old]			
alternative assessment type: Systematic			
subjects affected / exposed ^[12]	81 / 277 (29.24%)		
occurrences (all)	81		
Shivering			
alternative assessment type: Systematic			
subjects affected / exposed ^[13]	0 / 277 (0.00%)		
occurrences (all)	0		
Pain			
alternative assessment type: Systematic			
subjects affected / exposed ^[14]	116 / 277 (41.88%)		
occurrences (all)	116		
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	21 / 277 (7.58%) 21		
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	37 / 277 (13.36%) 37		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	26 / 277 (9.39%) 26		
Bronchitis subjects affected / exposed occurrences (all)	29 / 277 (10.47%) 29		

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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

[14] - 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 on Total Vaccinated cohort which included all subjects with the vaccine administration documented and symptom sheet completed.

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