Clinical trial results:
A phase II, randomized, open, partially controlled study to evaluate the safety and immunogenicity of different formulations of a pandemic influenza vaccine candidate (split virus formulation adjuvanted with AS03) given following a two-administration schedule (21 days apart) in children between 3 and 9 years of age.

Summary

EudraCT number	2006-001168-22
Trial protocol	GB ES
Global end of trial date	04 December 2009

Results information

Result version number	v2 (current)
This version publication date	06 June 2022
First version publication date	20 March 2015
Version creation reason	• Correction of full data set Correction of full data set and alingment between registries.

Trial information

Trial identification

Sponsor protocol code	107066 , 108498, 108500

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00502593
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 October 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 December 2009
Global end of trial reached?	Yes
Global end of trial date	04 December 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

•To evaluate the humoral immune response induced by the H5N1 vaccine candidate in terms of anti-haemagglutinin antibody titer.
•To evaluate the safety and reactogenicity of the H5N1 vaccine candidate in terms of solicited local and general adverse events, unsolicited adverse events and serious adverse events.

Protection of trial subjects:

As with all injectable vaccines, appropriate medical treatment was always readily available in case of anaphylactic reactions following the administration of the vaccine.
For this reason, the vaccinee remained under medical supervision for 30 minutes after vaccination.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	23 July 2007
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	Spain: 405
Worldwide total number of subjects	405
EEA total number of subjects	405

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	405
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

138 subjects were enrolled as part of the first 107066/Phase A part of this NCT00502593 study. This first part was then followed by a second and third part (Phases B [study 108498] and C [study 108500] during which 134 and 133 subjects were enrolled, respectively. Duration of the study was of 24 months for all subjects.

Pre-assignment

Screening details:

For safety reasons, subjects in each group were enrolled in a staggered manner, with enrolment taking place sequentially into 2 age strata, '6-9 years' 1st, and '3-5 years' next.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK1562902A–A Lot 1 3-5Y Group

Arm description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 1. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Arm type	Experimental
Investigational medicinal product name	Biological: Pandemic Influenza Vaccine (GSK1562902A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21, 3 different formulations are tested.

Arm title	Fluarix–A 3-5Y Group

Arm description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

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

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21.

Arm title	GSK1562902A–A Lot 1 6-9Y Group

Arm description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 1. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Arm type	Experimental

Investigational medicinal product name	Biological: Pandemic Influenza Vaccine (GSK1562902A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21, 3 different formulations are tested.

Arm title	Fluarix–A 6-9Y Group

Arm description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

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

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21.

Arm title	GSK1562902A–B Lot 2 3-5Y Group

Arm description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 2. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Arm type	Experimental
Investigational medicinal product name	Biological: Pandemic Influenza Vaccine (GSK1562902A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21, 3 different formulations are tested.

Arm title	Fluarix–B 3-5Y Group

Arm description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

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

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21.

Arm title	GSK1562902A–B Lot 2 6-9Y Group

Arm description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 2. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Arm type	Experimental

Investigational medicinal product name	Biological: Pandemic Influenza Vaccine (GSK1562902A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21, 3 different formulations are tested.

Arm title	Fluarix–B 6-9Y Group

Arm description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

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

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21.

Arm title	GSK1562902A–C Lot 3 3-5Y Group

Arm description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 3. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Arm type	Experimental
Investigational medicinal product name	Biological: Pandemic Influenza Vaccine (GSK1562902A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21, 3 different formulations are tested.

Arm title	Fluarix–C 3-5Y Group

Arm description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

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

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21.

Arm title	GSK1562902A–C Lot 3 6-9Y Group

Arm description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 3. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Arm type	Experimental

Investigational medicinal product name	Biological: Pandemic Influenza Vaccine (GSK1562902A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21, 3 different formulations are tested.

Arm title	Fluarix–C 6-9Y Group

Arm description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

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

Dosage and administration details:

2 doses, intramuscular injection on Days 0 and 21.

Number of subjects in period 1	GSK1562902A–A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A–A Lot 1 6-9Y Group
Started	51	18	51
Completed	48	16	41
Not completed	3	2	10
Withdrawn unspecified reason	1	1	3
Consent withdrawn by subject	-	-	6
Lost to follow-up	2	1	1

Number of subjects in period 1	Fluarix–A 6-9Y Group	GSK1562902A–B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group
Started	18	51	17
Completed	14	47	17
Not completed	4	4	0
Withdrawn unspecified reason	1	2	-
Consent withdrawn by subject	2	2	-
Lost to follow-up	1	-	-

Number of subjects in period 1	GSK1562902A–B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group	GSK1562902A–C Lot 3 3-5Y Group
Started	49	17	49
Completed	44	17	43
Not completed	5	0	6
Withdrawn unspecified reason	2	-	-
Consent withdrawn by subject	3	-	3

Lost to follow-up	-	-	3

Number of subjects in period 1	Fluarix–C 3-5Y Group	GSK1562902A–C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Started	17	49	18
Completed	17	47	18
Not completed	0	2	0
Withdrawn unspecified reason	-	-	-
Consent withdrawn by subject	-	1	-
Lost to follow-up	-	1	-

Baseline characteristics

Reporting groups

Reporting group title	GSK1562902A–A Lot 1 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 1. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–A 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–A Lot 1 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 1. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–A 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–B Lot 2 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 2. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–B 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–B Lot 2 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 2. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–B 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–C Lot 3 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 3. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–C 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–C Lot 3 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 3. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The GSK1562902A vaccine was

administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–C 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group values	GSK1562902A–A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A–A Lot 1 6-9Y Group
Number of subjects	51	18	51
Age categorical Units: Subjects			
Children (2-11 years)	51	18	51
Age continuous Units: years			
geometric mean	3.9	3.6	7.6
standard deviation	± 0.84	± 0.7	± 1.06
Gender categorical Units: Subjects			
Female	25	9	24
Male	26	9	27

Reporting group values	Fluarix–A 6-9Y Group	GSK1562902A–B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group
Number of subjects	18	51	17
Age categorical Units: Subjects			
Children (2-11 years)	18	51	17
Age continuous Units: years			
geometric mean	7.6	4.2	4.4
standard deviation	± 1.38	± 0.85	± 0.79
Gender categorical Units: Subjects			
Female	7	25	10
Male	11	26	7

Reporting group values	GSK1562902A–B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group	GSK1562902A–C Lot 3 3-5Y Group
Number of subjects	49	17	49
Age categorical Units: Subjects			
Children (2-11 years)	49	17	49
Age continuous Units: years			
geometric mean	7.3	7.2	4.2
standard deviation	± 1.28	± 1.2	± 0.85
Gender categorical Units: Subjects			
Female	19	3	22
Male	30	14	27

Reporting group values	Fluarix–C 3-5Y Group	GSK1562902A–C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Number of subjects	17	49	18
Age categorical Units: Subjects			
Children (2-11 years)	17	49	18
Age continuous Units: years			
geometric mean	3.9	7	7.4
standard deviation	± 0.93	± 1.06	± 0.98
Gender categorical Units: Subjects			
Female	11	18	9
Male	6	31	9

Reporting group values	Total		
Number of subjects	405		
Age categorical Units: Subjects			
Children (2-11 years)	405		
Age continuous Units: years			
geometric mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	182		
Male	223		

End points

End points reporting groups

Reporting group title	GSK1562902A–A Lot 1 3-5Y Group
Reporting group description:	
Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 1. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	Fluarix–A 3-5Y Group
Reporting group description:	
Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	GSK1562902A–A Lot 1 6-9Y Group
Reporting group description:	
Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 1. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	Fluarix–A 6-9Y Group
Reporting group description:	
Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	GSK1562902A–B Lot 2 3-5Y Group
Reporting group description:	
Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 2. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	Fluarix–B 3-5Y Group
Reporting group description:	
Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	GSK1562902A–B Lot 2 6-9Y Group
Reporting group description:	
Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 2. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	Fluarix–B 6-9Y Group
Reporting group description:	
Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	GSK1562902A–C Lot 3 3-5Y Group
Reporting group description:	
Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 3. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	Fluarix–C 3-5Y Group
Reporting group description:	
Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.	
Reporting group title	GSK1562902A–C Lot 3 6-9Y Group
Reporting group description:	
Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 3. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The GSK1562902A vaccine was	

administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–C 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Primary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease[1]

End point description:

Titers of serum HI antibodies are presented as geometric mean titers (GMTs). The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO). The cut-off of the assay was the seropositivity cut-off value of 1:10.

End point type	Primary

End point timeframe:

At Day 0

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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[2]	15[3]	43[4]	15[5]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
A/INDO	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

Notes:

[2] - The data was not computed for titers below the cut-off value for titer calculation.

[3] - The data was not computed for titers below the cut-off value for titer calculation.

[4] - The data was not computed for titers below the cut-off value for titer calculation.

[5] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[6]	16[7]	45[8]	17[9]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	5.1 (4.9 to 5.4)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
A/INDO	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

Notes:

[6] - The data was not computed for titers below the cut-off value for titer calculation.

[7] - The data was not computed for titers below the cut-off value for titer calculation.

[8] - The data was not computed for titers below the cut-off value for titer calculation.

[9] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44[10]	15[11]	43[12]	13[13]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
A/INDO	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

Notes:

[10] - The data was not computed for titers below the cut-off value for titer calculation.

[11] - The data was not computed for titers below the cut-off value for titer calculation.

[12] - The data was not computed for titers below the cut-off value for titer calculation.

[13] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease[14]

End point description:

Titers of serum HI antibodies are presented as geometric mean titers (GMTs). The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO). The cut-off of the assay was the seropositivity cut-off value of 1:10.

End point type	Primary

End point timeframe:

At Day 21

Notes:

[14] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	15[15]	43	15[16]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	8.7 (6.2 to 12.3)	0 (0 to 0)	12.1 (8.4 to 17.5)	0 (0 to 0)
A/INDO	5.2 (4.9 to 5.6)	0 (0 to 0)	5.2 (4.8 to 5.8)	0 (0 to 0)

Notes:

[15] - The data was not computed for titers below the cut-off value for titer calculation.

[16] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	16[17]	45	17[18]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	22.7 (14.6 to 35.3)	0 (0 to 0)	23.7 (14.3 to 39.1)	0 (0 to 0)
A/INDO	5.5 (4.9 to 6.2)	0 (0 to 0)	5.3 (4.9 to 5.8)	0 (0 to 0)

Notes:

[17] - The data was not computed for titers below the cut-off value for titer calculation.

[18] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	15[19]	30	9[20]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	25 (16 to 39.3)	5.7 (4.3 to 7.7)	27.3 (16.2 to 46)	0 (0 to 0)
A/INDO	7.7 (6 to 9.8)	0 (0 to 0)	6 (5 to 7.2)	0 (0 to 0)

Notes:

[19] - The data was not computed for titers below the cut-off value for titer calculation.

[20] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease[21]

End point description:

Titers are presented as geometric mean titers (GMTs). The 2 flu strains assessed were A/Vietnam/1194/2004 (A/VIET) and A/Indonesia/5/2005 (A/INDO). The cut-off of the assay was the seropositivity cut-off value of 1:10.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[21] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	15[22]	43	15[23]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	392.7 (280.4 to 550.2)	0 (0 to 0)	540.3 (424.5 to 687.7)	0 (0 to 0)
A/INDO	53.5 (35 to 81.7)	0 (0 to 0)	60.8 (38.7 to 95.5)	0 (0 to 0)

Notes:

[22] - The data was not computed for titers below the cut-off value for titer calculation.

[23] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	16[24]	45	17[25]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	678.1 (475.7 to 966.6)	0 (0 to 0)	615.8 (429 to 884)	0 (0 to 0)
A/INDO	73.7 (45.2 to 120.3)	0 (0 to 0)	64.9 (38.7 to 108.9)	0 (0 to 0)

Notes:

[24] - The data was not computed for titers below the cut-off value for titer calculation.

[25] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	15[26]	43	13[27]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	956.4 (769.2 to 1189.3)	0 (0 to 0)	883.5 (737.3 to 1058.6)	0 (0 to 0)
A/INDO	167.9 (121.7 to 231.5)	0 (0 to 0)	92.5 (59.3 to 144.2)	0 (0 to 0)

Notes:

[26] - The data was not computed for titers below the cut-off value for titer calculation.

[27] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease[28]

End point description:

Titers of serum HI antibodies are presented as geometric mean titers (GMTs). The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO). The cut-off of the assay was the seropositivity cut-off value of 1:10.

End point type	Primary

End point timeframe:

At Month 6

Notes:

[28] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	15[29]	44	14[30]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	29.3 (19.2 to 44.6)	5.9 (4.2 to 8.3)	33.4 (21.2 to 52.7)	0 (0 to 0)
A/INDO	6.9 (5.6 to 8.4)	0 (0 to 0)	6.6 (5.2 to 8.4)	0 (0 to 0)

Notes:

[29] - The data was not computed for titers below the cut-off value for titer calculation.

[30] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	16[31]	45	17[32]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	46.3 (29.8 to 72)	0 (0 to 0)	43.2 (27.9 to 66.8)	0 (0 to 0)
A/INDO	21.7 (14.3 to 33)	0 (0 to 0)	11.9 (8.4 to 16.9)	0 (0 to 0)

Notes:

[31] - The data was not computed for titers below the cut-off value for titer calculation.

[32] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	11[33]	41	16[34]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	80 (47 to 136.4)	0 (0 to 0)	61.5 (38.9 to 97.3)	0 (0 to 0)
A/INDO	42.5 (23.7 to 76.3)	0 (0 to 0)	36.8 (22.3 to 60.6)	0 (0 to 0)

Notes:

[33] - The data was not computed for titers below the cut-off value for titer calculation.

[34] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease[35]

End point description:

Titers are presented as geometric mean titers (GMTs). The 2 flu strains assessed were A/Vietnam/1194/2004 (A/VIET) and A/Indonesia/5/2005 (A/INDO). The cut-off of the assay was the seropositivity cut-off value of 1:10

End point type	Primary

End point timeframe:

At Month 12

Notes:

[35] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	14[36]	37	14
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	13.9 (9.7 to 20)	0 (0 to 0)	12 (8 to 18.1)	5.8 (4.2 to 8)
A/INDO	13 (9.1 to 18.7)	0 (0 to 0)	10.5 (7 to 15.8)	5.5 (4.5 to 6.8)

Notes:

[36] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	16	43	16
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	19.8 (13.6 to 28.8)	5.2 (4.8 to 5.7)	22.4 (15.4 to 32.5)	5.2 (4.8 to 5.7)
A/INDO	16.4 (11.4 to 23.5)	5.9 (4.5 to 7.9)	15 (11.1 to 20.1)	6.5 (5.2 to 8.2)

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	10[37]	35	13[38]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	23.9 (15.1 to 37.8)	0 (0 to 0)	27.7 (19.1 to 40.4)	5.4 (4.6 to 6.4)
A/INDO	18.5 (11.5 to 29.9)	0 (0 to 0)	20.4 (13.4 to 31.1)	0 (0 to 0)

Notes:

[37] - The data was not computed for titers below the cut-off value for titer calculation.

[38] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease

End point title	Titers for serum Hemagglutination Inhibition (HI) antibodies against 2 strains of influenza disease[39]

End point description:

Titers of serum HI antibodies are presented as geometric mean titers (GMTs). The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO). The cut-off of the assay was the seropositivity cut-off value of 1:10.

End point type	Primary

End point timeframe:

At Month 24

Notes:

[39] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	13[40]	37	11[41]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	14.9 (10.3 to 21.5)	0 (0 to 0)	13.2 (9.1 to 19.2)	0 (0 to 0)
A/INDO	10.1 (7.7 to 13.4)	0 (0 to 0)	7.7 (5.9 to 10)	0 (0 to 0)

Notes:

[40] - The data was not computed for titers below the cut-off value for titer calculation.

[41] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	16	42	16[42]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	52.2 (33.6 to 81.1)	6.8 (4.7 to 9.7)	20.1 (13.9 to 29.3)	0 (0 to 0)
A/INDO	22.7 (15.2 to 33.7)	5.3 (4.6 to 6.1)	8.7 (7 to 10.8)	0 (0 to 0)

Notes:

[42] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	10[43]	34	13[44]
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET	55.8 (33.2 to 93.8)	6.6 (3.5 to 12.4)	36.5 (24.8 to 53.8)	6.2 (3.9 to 9.8)
A/INDO	27.5 (16.1 to 47)	0 (0 to 0)	18.2 (12.1 to 27.6)	0 (0 to 0)

Notes:

[43] - The data was not computed for titers below the cut-off value for titer calculation.

[44] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroconverted subjects against 2 strains of influenza disease

End point title	Number of seroconverted subjects against 2 strains of influenza disease[45]

End point description:

A seroconverted subject was a subject with a pre-vaccination serum haemagglutination-inhibition (HI) antibody titer below (<) 1:10 and a post-vaccination HI antibody titer above than or equal to (≥)1:40 or a pre-vaccination HI antibody titer ≥ 1:10 and at least four-fold increase in post-vaccination HI antibody titer. The 2 strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Day 21

Notes:

[45] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	15	43	15
Units: Subjects				
A/VIET	6	0	13	0
A/INDO	0	0	1	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	16	45	17
Units: Subjects				
A/VIET	20	0	19	0
A/INDO	0	0	0	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	15	30	9
Units: Subjects				
A/VIET	20	1	17	0
A/INDO	3	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroconverted Subjects Against 2 Strains of Influenza Disease

End point title	Number of Seroconverted Subjects Against 2 Strains of Influenza Disease[46]

End point description:

A seroconverted subject was a subject with a pre-vaccination serum haemagglutination-inhibition (HI) antibody titer < 1:10 and a post-vaccination HI antibody titer ≥1:40 or a pre-vaccination HI antibody titer ≥ 1:10 and at least four-fold increase in post-vaccination HI antibody titer. The 2 strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Day 42

Notes:

[46] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	15	43	15
Units: Subjects				
A/VIET	47	0	43	0
A/INDO	35	0	32	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	16	45	17
Units: Subjects				
A/VIET	41	0	44	0
A/INDO	32	0	31	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	15	43	13
Units: Subjects				
A/VIET	44	0	43	0
A/INDO	42	0	34	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroconverted Subjects Against 2 Strains of Influenza Disease

End point title	Number of Seroconverted Subjects Against 2 Strains of Influenza Disease[47]

End point description:

A seroconverted subject was a subject with a pre-vaccination serum haemagglutination-inhibition (HI) antibody titer < 1:10 and a post-vaccination HI antibody titer ≥1:40 or a pre-vaccination HI antibody titer ≥ 1:10 and at least four-fold increase in post-vaccination HI antibody titer. The 2 strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Month 6

Notes:

[47] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	15	41	14
Units: Subjects				
A/VIET	28	1	25	0
A/INDO	3	0	1	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	16	45	17
Units: Subjects				
A/VIET	32	0	31	0
A/INDO	23	0	12	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	11	41	16
Units: Subjects				
A/VIET	24	0	32	0
A/INDO	20	0	25	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroconverted Subjects Against 2 Strains of Influenza Disease

End point title	Number of Seroconverted Subjects Against 2 Strains of Influenza Disease[48]

End point description:

A seroconverted subject was a subject with a pre-vaccination serum haemagglutination-inhibition (HI) antibody titer < 1:10 and a post-vaccination HI antibody titer ≥1:40 or a pre-vaccination HI antibody titer ≥ 1:10 and at least four-fold increase in post-vaccination HI antibody titer. The 2 strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Month 12

Notes:

[48] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	14	37	14
Units: Subjects				
A/VIET	18	0	8	1
A/INDO	17	0	6	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	16	43	16
Units: Subjects				
A/VIET	17	0	20	0
A/INDO	16	1	7	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	10	35	13
Units: Subjects				
A/VIET	13	0	22	0
A/INDO	12	0	15	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroconverted Subjects Against 2 Strains of Influenza Disease

End point title	Number of Seroconverted Subjects Against 2 Strains of Influenza Disease[49]

End point description:

A seroconverted subject was a subject with a pre-vaccination serum haemagglutination-inhibition (HI) antibody titer < 1:10 and a post-vaccination HI antibody titer ≥1:40 or a pre-vaccination HI antibody titer ≥ 1:10 and at least four-fold increase in post-vaccination HI antibody titer. The 2 strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Month 24

Notes:

[49] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	13	35	11
Units: Subjects				
A/VIET	18	0	8	0
A/INDO	5	0	3	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	16	42	16
Units: Subjects				
A/VIET	30	1	18	0
A/INDO	19	0	2	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	10	34	13
Units: Subjects				
A/VIET	19	1	23	1
A/INDO	14	0	10	0

Statistical analyses

No statistical analyses for this end point

Primary: Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease

End point title	Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease[50]

End point description:

The seroconversion factor (SCF) was defined as the fold increase in serum Hemagglutination Inhibition (HI) geometric mean titers (GMTs) post vaccination compared to Day 0. The 2 strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Day 21

Notes:

[50] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[51]	15[52]	43[53]	15[54]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	1.7 (1.2 to 2.5)	0 (0 to 0)	2.4 (1.7 to 3.5)	0 (0 to 0)
A/INDO	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

Notes:

[51] - The data was not computed for titers below the cut-off value for titer calculation.

[52] - The data was not computed for titers below the cut-off value for titer calculation.

[53] - The data was not computed for titers below the cut-off value for titer calculation.

[54] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	16[55]	45	17[56]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	4.4 (2.9 to 6.8)	0 (0 to 0)	4.7 (2.9 to 7.8)	0 (0 to 0)
A/INDO	1.1 (1 to 1.2)	0 (0 to 0)	1.1 (1 to 1.2)	0 (0 to 0)

Notes:

[55] - The data was not computed for titers below the cut-off value for titer calculation.

[56] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	15[57]	30	9[58]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	5 (3.2 to 7.9)	1.1 (0.9 to 1.5)	5.5 (3.2 to 9.2)	0 (0 to 0)
A/INDO	1.5 (1.2 to 2)	0 (0 to 0)	1.2 (1 to 1.4)	0 (0 to 0)

Notes:

[57] - The data was not computed for titers below the cut-off value for titer calculation.

[58] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease

End point title	Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease[59]

End point description:

The seroconversion factor (SCF) was defined as the fold increase in serum Hemagglutination Inhibition (HI) geometric mean titers (GMTs) post vaccination compared to Day 0. The 2 strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Day 42

Notes:

[59] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	15[60]	43	15[61]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	78.5 (56.1 to 110)	0 (0 to 0)	108.1 (84.9 to 137.5)	0 (0 to 0)
A/INDO	10.7 (7 to 16.3)	0 (0 to 0)	12.2 (7.7 to 19.1)	0 (0 to 0)

Notes:

[60] - The data was not computed for titers below the cut-off value for titer calculation.

[61] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	16[62]	45	17[63]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	132.3 (91.8 to 190.7)	0 (0 to 0)	123.2 (85.8 to 176.8)	0 (0 to 0)
A/INDO	14.7 (9 to 24.1)	0 (0 to 0)	13 (7.7 to 21.8)	0 (0 to 0)

Notes:

[62] - The data was not computed for titers below the cut-off value for titer calculation.

[63] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	15[64]	43	13[65]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	191.3 (153.8 to 237.9)	0 (0 to 0)	176.7 (147.5 to 211.7)	0 (0 to 0)
A/INDO	33.6 (24.3 to 46.3)	0 (0 to 0)	18.5 (11.9 to 28.8)	0 (0 to 0)

Notes:

[64] - The data was not computed for titers below the cut-off value for titer calculation.

[65] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease

End point title	Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease[66]

End point description:

The seroconversion factor (SCF) was defined as the fold increase in serum Hemagglutination Inhibition (HI) geometric mean titers (GMTs) post vaccination compared to Day 0. The 2 strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Month 6

Notes:

[66] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	15[67]	41	14[68]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	5.9 (3.8 to 8.9)	1.2 (0.8 to 1.7)	6.1 (3.8 to 9.7)	0 (0 to 0)
A/INDO	1.4 (1.1 to 1.7)	0 (0 to 0)	1.2 (1 to 1.5)	1.2 (1 to 1.5)

Notes:

[67] - The data was not computed for titers below the cut-off value for titer calculation.

[68] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	16[69]	45	17[70]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	9.1 (5.8 to 14.1)	0 (0 to 0)	8.6 (5.6 to 13.4)	0 (0 to 0)
A/INDO	4.3 (2.9 to 6.6)	1.1 (0.9 to 1.4)	2.4 (1.7 to 3.4)	0 (0 to 0)

Notes:

[69] - The data was not computed for titers below the cut-off value for titer calculation.

[70] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	11[71]	41	16[72]
Units: units: Fold				
geometric mean (confidence interval				

95%)				
A/VIET	16 (9.4 to 27.3)	0 (0 to 0)	12.3 (7.8 to 19.5)	0 (0 to 0)
A/INDO	8.5 (4.7 to 15.3)	0 (0 to 0)	7.4 (4.5 to 12.1)	0 (0 to 0)

Notes:

[71] - The data was not computed for titers below the cut-off value for titer calculation.

[72] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease

End point title	Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease[73]

End point description:

The seroconversion factor (SCF) was defined as the fold increase in serum Hemagglutination Inhibition (HI) geometric mean titers (GMTs) post vaccination compared to Day 0. The 2 flu strains assessed were A/Vietnam/1194/2004 (A/VIET) and A/Indonesia/5/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Month 12

Notes:

[73] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	14[74]	35	14
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET (N=47;14;35;14;40;16;43;16;27;10;35	2.8 (1.9 to 4)	0 (0 to 0)	2.2 (1.5 to 3.3)	1.2 (0.8 to 1.6)
A/INDO (N=47;14;34;14;40;16;43;16;27;10;35	2.6 (1.8 to 3.7)	0 (0 to 0)	1.9 (1.3 to 2.8)	1.1 (0.9 to 1.4)

Notes:

[74] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	16	43	16
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET (N=47;14;35;14;40;16;43;16;27;10;35	4 (2.7 to 5.8)	1 (1 to 1.1)	4.5 (3.1 to 6.5)	1 (1 to 1.1)
A/INDO (N=47;14;34;14;40;16;43;16;27;10;35	3.3 (2.3 to 4.7)	1.2 (0.9 to 1.6)	3 (2.2 to 4)	1.3 (1 to 1.6)

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	10[75]	35	13[76]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET (N=47;14;35;14;40;16;43;16;27;10;35	4.8 (3 to 7.6)	0 (0 to 0)	5.5 (3.8 to 8.1)	1.1 (0.9 to 1.3)
A/INDO (N=47;14;34;14;40;16;43;16;27;10;35	3.7 (2.3 to 6)	0 (0 to 0)	4.1 (2.7 to 6.2)	0 (0 to 0)

Notes:

[75] - The data was not computed for titers below the cut-off value for titer calculation.

[76] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease

End point title	Seroconversion Factor for Hemagglutination Inhibition (HI) Antibodies Against 2 Strains of Influenza Disease[77]

End point description:

The seroconversion factor (SCF) was defined as the fold increase in serum Hemagglutination Inhibition (HI) geometric mean titers (GMTs) post vaccination compared to Day 0. The 2 flu strains assessed were A/Vietnam/1194/2004 (A/VIET) and A/Indonesia/5/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Month 24

Notes:

[77] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	13[78]	35	11[79]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	3 (2.1 to 4.3)	0 (0 to 0)	2.5 (1.7 to 3.6)	0 (0 to 0)
A/INDO	2 (1.5 to 2.7)	0 (0 to 0)	1.5 (1.1 to 1.9)	0 (0 to 0)

Notes:

[78] - The data was not computed for titers below the cut-off value for titer calculation.

[79] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –B Lot 2 3-5Y	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y	Fluarix–B 6-9Y Group

	Group		Group	
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	16	42	16[80]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	10.4 (6.7 to 16.2)	1.4 (0.9 to 1.9)	4 (2.8 to 5.9)	0 (0 to 0)
A/INDO	4.5 (3 to 6.7)	1.1 (0.9 to 1.2)	1.7 (1.4 to 2.2)	0 (0 to 0)

Notes:

[80] - The data was not computed for titers below the cut-off value for titer calculation.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	10[81]	34	13[82]
Units: units: Fold				
geometric mean (confidence interval 95%)				
A/VIET	11.2 (6.6 to 18.8)	1.3 (0.7 to 2.5)	7.3 (5 to 10.8)	1.2 (0.8 to 2)
A/INDO	5.5 (3.2 to 9.4)	0 (0 to 0)	3.6 (2.4 to 5.5)	0 (0 to 0)

Notes:

[81] - The data was not computed for titers below the cut-off value for titer calculation.

[82] - The data was not computed for titers below the cut-off value for titer calculation.

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease

End point title	Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease[83]

End point description:

A seroprotected subject was defined as a vaccinated subject with a haemagglutination-inhibition (HI) antibody titer above or equal to the seroprotection threshold of 1:40. The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/5/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Day 0

Notes:

[83] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	15	43	15
Units: Subjects				
A/VIET	0	0	0	0

A/INDO	0	0	0	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	17	42	16
Units: Subjects				
A/VIET	0	0	0	0
A/INDO	0	0	0	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	15	43	13
Units: Subjects				
A/VIET	0	0	0	0
A/INDO	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease

End point title	Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease[84]

End point description:

A seroprotected subject was defined as a vaccinated subject with a haemagglutination-inhibition (HI) antibody titer above or equal to the seroprotection threshold of 1:40. The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/5/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Day 21

Notes:

[84] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	15	43	15
Units: Subjects				
A/VIET	6	0	13	0
A/INDO	0	0	1	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	16	45	17
Units: Subjects				
A/VIET	20	0	19	0
A/INDO	0	0	0	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	15	30	9
Units: Subjects				
A/VIET	20	1	17	0
A/INDO	3	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease

End point title	Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease[85]

End point description:

A seroprotected subject was defined as a vaccinated subject with a haemagglutination-inhibition (HI) antibody titer above or equal to the seroprotection threshold of 1:40. The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/5/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Day 42

Notes:

[85] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	15	43	15
Units: Subjects				
A/VIET	47	0	43	0
A/INDO	35	0	32	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	16	45	17
Units: Subjects				
A/VIET	41	0	44	0
A/INDO	32	0	31	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	15	43	13
Units: Subjects				
A/VIET	44	0	43	0
A/INDO	42	0	34	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease

End point title	Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease[86]

End point description:

A seroprotected subject was defined as a vaccinated subject with a haemagglutination-inhibition (HI) antibody titer above or equal to the seroprotection threshold of 1:40. The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/5/2005 (A/INDO)

End point type	Primary

End point timeframe:

At Month 6

Notes:

[86] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	15	44	14
Units: Subjects				
A/VIET	28	1	28	0
A/INDO	3	0	2	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	16	45	17
Units: Subjects				
A/VIET	33	0	31	0
A/INDO	23	0	12	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	11	41	16
Units: Subjects				
A/VIET	24	0	32	0
A/INDO	20	0	25	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease

End point title	Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease[87]

End point description:

A seroprotected subject was defined as a vaccinated subject with a haemagglutination-inhibition (HI) antibody titer above or equal to the seroprotection threshold of 1:40. The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/5/2005 (A/INDO)

End point type	Primary

End point timeframe:

At Month 12

Notes:

[87] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	14	37	14
Units: Subjects				
A/VIET (N=47,14,37,14,40,16,43,16,27,10,35,	18	0	9	1
A/INDO (N=47,14,36,14,40,16,43,16,27,10,35,	17	0	7	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	16	43	16
Units: Subjects				
A/VIET (N=47,14,37,14,40,16,43,16,27,10,35,	17	0	20	0
A/INDO (N=47,14,36,14,40,16,43,16,27,10,35,	16	1	7	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	10	35	13
Units: Subjects				
A/VIET (N=47,14,37,14,40,16,43,16,27,10,35,	13	0	22	0
A/INDO (N=47,14,36,14,40,16,43,16,27,10,35,	12	0	15	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease

End point title	Number of Seroprotected Subjects Against the 2 Strains of Influenza Disease[88]

End point description:

A seroprotected subject was defined as a vaccinated subject with a serum HI antibody titer ≥ 1:40, a level of HI antibody that has been viewed as correlating with protection against influenza. The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/5/2005 (A/INDO).

End point type	Primary

End point timeframe:

At Month 24

Notes:

[88] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	13	37	11
Units: Subjects				
A/VIET	18	0	9	0
A/INDO	5	0	4	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	16	42	16
Units: Subjects				
A/VIET	30	1	18	0
A/INDO	19	0	2	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	10	34	13
Units: Subjects				
A/VIET	19	1	23	1
A/INDO	14	0	10	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms

End point title	Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms[89][90]

End point description:

Assessed solicited local symptoms were ecchymosis, induration, pain, redness and swelling at the injection site. Any = occurrence of a symptom regardless of intensity. Grade 3 pain = significant pain at rest/ that prevented normal activities. Grade 3 ecchymosis/induration/redness/swelling = ecchymosis/induration/redness/swelling larger than (>) 100 millimeters (mm). All solicited local symptoms were considered to be related to study vaccination. This outcome presents results from subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

During the 7 day follow-up period after each vaccination

Notes:

[89] - 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.
[90] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	18
Units: Subjects				
Any ecchymosis	9	3	3	2
Ecchymosis >50mm	0	0	0	0
Any induration	7	1	12	6
Induration >50mm	1	0	0	1
Any pain	31	7	44	12
Grade 3 pain	2	0	5	0
Any redness	10	2	12	5
Redness >50mm	0	0	0	0
Any swelling	10	1	14	7
Swelling >50mm	1	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms

End point title	Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms[91][92]

End point description:

Assessed solicited local symptoms were ecchymosis, induration, pain, redness and swelling at the injection site. Any = occurrence of a symptom regardless of intensity. Grade 3 pain = significant pain at rest/ that prevented normal activities. Grade 3 ecchymosis/induration/redness/swelling = ecchymosis/induration/redness/swelling larger than (>) 100 millimeters (mm). All solicited local symptoms were considered to be related to study vaccination. This outcome presents results from subjects participating in Phase C of the study.

End point type	Primary

End point timeframe:

During the 7-day follow-up period after each vaccination

Notes:

[91] - 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.

[92] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	17	49	18
Units: Subjects				
Any ecchymosis	4	0	0	2
Ecchymosys >50mm	0	0	0	0
Any induration	14	0	10	1
Induration >50mm	1	0	1	0
Any pain	37	7	44	15
Grade 3 pain	5	0	3	0
Any redness	16	2	6	1
Redness >50mm	1	0	2	0
Any swelling	18	2	14	3
Swelling >50mm	2	0	2	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Any, Grade 3 and Related Solicited General Symptoms

End point title	Number of Subjects With Any, Grade 3 and Related Solicited General Symptoms[93][94]

End point description:

Assessed solicited general symptoms were drowsiness, fever (axillary temperature above or equal (≥) 37.5°C), irritability, loss of appetite, shivering, sweating and vomiting. Any = occurrence of a symptom regardless of intensity or relationship to vaccination. Grade 3 = general symptom that prevented normal activity. Grade 3 temperature = axillary temperature > 39.0°C. Related = symptom assessed as causally related to study vaccination. This outcome presents results for subjects aged between 3 and 5 years participating in Phases A, B and C of the study.

End point type	Primary

End point timeframe:

During the 7-day (Days 0-6) follow-up period after any vaccination
Safety Issue No

Notes:

[93] - 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.
[94] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	17
Units: Subjects				
Any drowsiness	7	1	9	1
Grade 3 drowsiness	1	0	1	0
Related drowsiness	6	1	6	0
Fever (Axillary) >=37.5 deg C	8	0	10	2
Fever >39degC (Axillary)	2	0	0	1
Related fever (Axillary)	6	0	5	1
Any irritability	9	1	13	2
Grade 3 irritability	0	0	0	0
Related irritability	7	1	9	1
Any loss of appetite	12	1	8	1
Grade 3 loss of appetite	3	0	1	0
Related loss of appetite	4	1	5	1
Any shivering	1	0	4	1
Grade 3 shivering	0	0	0	0
Related shivering	1	0	2	0
Any sweating	4	0	1	0
Grade 3 sweating	0	0	0	0
Related sweating	2	0	1	0
Any vomiting	7	0	6	0
Grade 3 vomiting	0	0	1	0
Related vomiting	3	0	2	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	17		
Units: Subjects				
Any drowsiness	12	1		
Grade 3 drowsiness	2	0		
Related drowsiness	12	1		
Fever (Axillary) >=37.5 deg C	18	0		
Fever >39degC (Axillary)	5	0		
Related fever (Axillary)	17	0		
Any irritability	18	0		
Grade 3 irritability	1	0		
Related irritability	15	0		
Any loss of appetite	15	1		
Grade 3 loss of appetite	5	0		
Related loss of appetite	13	1		
Any shivering	10	1		
Grade 3 shivering	0	0		
Related shivering	9	1		
Any sweating	4	0		

Grade 3 sweating	1	0		
Related sweating	3	0		
Any vomiting	6	1		
Grade 3 vomiting	0	0		
Related vomiting	3	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms

End point title	Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms[95][96]

End point description:

Assessed solicited local symptoms were ecchymosis, induration, pain, redness and swelling at the injection site. Any = occurrence of a symptom regardless of intensity. Grade 3 pain = significant pain at rest/ that prevented normal activities. Grade 3 ecchymosis/induration/redness/swelling = ecchymosis/induration/redness/swelling larger than (>) 100 millimeters (mm). All solicited local symptoms were considered to be related to study vaccination. This outcome presents results from subjects participating to Phase B of the study.

End point type	Primary

End point timeframe:

During the 7-day follow-up period after each vaccination

Notes:

[95] - 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.
[96] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Any, Grade 3 and Related Solicited Local Symptoms), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	49	17
Units: Subjects				
Any ecchymosis	4	0	4	1
Ecchymosis >50mm	0	0	0	0
Any induration	4	1	6	1
Induration >50mm	0	0	1	0
Any pain	27	3	36	9
Grade 3 pain	5	0	3	0
Any redness	6	4	6	3
Redness >50mm	1	0	0	0
Any swelling	9	2	10	2
Swelling >50mm	0	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Any, Grade 3 and Related Solicited General Symptoms

End point title	Number of Subjects With Any, Grade 3 and Related Solicited General Symptoms[97][98]

End point description:

Solicited general symptoms were arthralgia, fatigue, headache, muscle aches, shivering and fever, assessed as oral temperature above or equal (≥) 37.0 degrees Celsius (°C). Any = occurrence of a symptom regardless of intensity or relationship to vaccination. Grade 3 = general symptom that prevented normal activity, everyday activities, or required intervention of a physician/healthcare provider. Grade 3 fever= oral temperature ≥ 39.0°C. Related = symptom assessed as causally related to study vaccination. This outcome presents results related to subjects aged 6 to 9 years participating in the study phases A, B and C.

End point type	Primary

End point timeframe:

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

Notes:

[97] - 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.
[98] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Any, Grade 3 and Related Solicited General Symptoms), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	49	17
Units: Subjects				
Any arthralgia	6	3	7	0
Grade 3 arthralgia	0	0	1	0
Related arthralgia	6	3	7	0
Any fatigue	7	1	6	1
Grade 3 fatigue	0	0	0	0
Related fatigue	7	1	6	1
Fever >=37.5 deg C	7	3	3	0
Fever >39.0 deg C	0	1	1	0
Related fever	6	2	1	0
Any gastrointestinal symptoms	9	5	4	5
Grade 3 gastrointestinal symptoms	1	0	1	0
Related gastrointestinal symptoms	8	4	2	2
Any headache	20	5	11	2

Grade 3 headache	2	0	2	0
Related headache	16	3	8	2
Any myalgia	10	3	11	2
Grade 3 myalgia	1	0	1	0
Related myalgia	9	3	11	1
Any shivering	3	1	7	0
Grade 3 Shivering	0	0	0	0
Related Shivering	3	1	5	0
Any sweating	3	2	3	2
Grade 3 sweating	0	0	0	0
Related sweating	3	2	1	1

End point values	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	18		
Units: Subjects				
Any arthralgia	9	2		
Grade 3 arthralgia	0	0		
Related arthralgia	7	2		
Any fatigue	11	2		
Grade 3 fatigue	1	0		
Related fatigue	11	2		
Fever >=37.5 deg C	18	0		
Fever >39.0 deg C	7	0		
Related fever	17	0		
Any gastrointestinal symptoms	16	5		
Grade 3 gastrointestinal symptoms	0	1		
Related gastrointestinal symptoms	13	3		
Any headache	25	3		
Grade 3 headache	3	0		
Related headache	22	3		
Any myalgia	13	2		
Grade 3 myalgia	1	0		
Related myalgia	11	2		
Any shivering	13	3		
Grade 3 Shivering	2	0		
Related Shivering	13	2		
Any sweating	6	1		
Grade 3 sweating	0	0		
Related sweating	6	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Serious Adverse Events (SAEs)

End point title	Number of Subjects With Serious Adverse Events (SAEs)[99]

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. Any SAE = any SAE regardless of intensity or relationship to vaccination.

End point type	Primary

End point timeframe:

During the entire study (Day 0 to Month 24)

Notes:

[99] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	18
Units: Subjects				
Any SAE(s)	0	0	0	0

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	49	17
Units: Subjects				
Any SAE(s)	0	1	0	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	17	49	18
Units: Subjects				
Any SAE(s)	2	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Any, Grade 3 and Related Unsolicited Adverse Events

End point title	Number of Subjects With Any, Grade 3 and Related Unsolicited Adverse Events[100]

End point description:

An unsolicited adverse event is any adverse event (i.e. any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product) reported in addition to those solicited during the clinical study. Also any "solicited" symptom with onset outside the specified period of follow-up for solicited symptoms will be reported as an unsolicited adverse event. Grade 3 AE = AE that prevented normal activity, everyday activities, or required intervention of a physician/healthcare provider. Related = symptom assessed as causally related to study vaccination.

End point type	Primary

End point timeframe:

During a 21 day follow-up period after the first vaccination, during a 30-day follow-up period after the second vaccination

Notes:

[100] - 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	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	18
Units: Subjects				
Subjects with any AE(s)	29	12	10	5
Subjects with any Grade 3 AE(s)	4	1	1	0
Subjects with any related AE(s)	6	2	2	1

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	49	17
Units: Subjects				
Subjects with any AE(s)	28	9	19	6
Subjects with any Grade 3 AE(s)	3	0	0	1
Subjects with any related AE(s)	3	1	4	1

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	17	49	18
Units: Subjects				
Subjects with any AE(s)	26	8	27	6
Subjects with any Grade 3 AE(s)	3	0	1	1
Subjects with any related AE(s)	9	0	3	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT) for Subjects in Study Phase A

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT) for Subjects in Study Phase A[101][102]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for ALT for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 21 and 42 and Months 6, 12 and 24

Notes:

[101] - 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.
[102] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	17	49	18
Units: Subjects				
ALT,Unknown,Day 21,Below[N=1,0,0,1]	0	0	0	0
ALT,Unknown,Day 21,Normal [N=1,0,0,1]	1	0	0	1
ALT,Unknown,Day 21,Above [N=1,0,0,1]	0	0	0	0
ALT,Unknown,Day 21,Unknown [N=1,0,0,1]	0	0	0	0
ALT,Normal,Day 21,Below [N=48,17,48,17]	0	0	0	0
ALT,Normal,Day 21,Normal [N=48,17,48,17]	47	16	44	17
ALT,Normal,Day 21,Above [N=48,17,48,17]	0	0	0	0
ALT,Normal,Day 21,Unknown [N=48,17,48,17]	1	1	4	0
ALT,Unknown,Day 42,Below [N=1,0,0,1]	0	0	0	0
ALT,Unknown,Day 42,Normal [N=1,0,0,1]	1	0	0	1
ALT,Unknown,Day 42,Above [N=1,0,0,1]	0	0	0	0
ALT,Unknown,Day 42,Unknown [N=1,0,0,1]	0	0	0	0

ALT,Normal,Day 42,Below [N=49,17,49,17]	0	0	0	0
ALT,Normal,Day 42,Normal [N=49,17,49,17]	48	15	45	15
ALT,Normal,Day 42,Above [N=49,17,49,17]	0	1	0	0
ALT,Normal,Day 42,Unknown [N=49,17,49,17]	1	1	4	2
ALT,Unknown, Month 6,Below [N=1,0,0,1]	0	0	0	0
ALT,Unknown, Month 6,Normal [N=1,0,0,1]	1	0	0	1
ALT,Unknown, Month 6,Above [N=1,0,0,1]	0	0	0	0
ALT,Unknown, Month 6,Unknown [N=1,0,0,1]	0	0	0	0
ALT,Normal, Month 6,Below [N=49,17,47,16]	0	0	0	0
ALT,Normal, Month 6,Normal [N=49,17,47,16]	47	15	42	16
ALT,Normal, Month 6,Above [N=49,17,47,16]	1	0	1	0
ALT,Normal, Month 6,Unknown [N=49,17,47,16]	1	2	4	0
ALT,Unknown, Month 12,Below[N=1,0,0,1]	0	0	0	0
ALT,Unknown, Month 12,Normal[N=1,0,0,1]	1	0	0	1
ALT,Unknown, Month 12,Unknown[N=1,0,0,1]	0	0	0	0
ALT,Unknown, Month 12,Above[N=1,0,0,1]	0	0	0	0
ALT,Normal, Month 12,Below [N=49,17,44,16]	0	0	0	0
ALT,Normal, Month 12,Normal[N=49,17,44,16]	45	17	41	16
ALT,Normal, Month 12,Above[N=49,17,44,16]	1	0	1	0
ALT,Normal, Month 12,Unknown[N=49,17,44,16]	3	0	2	0
ALT,Unknown, Month 24,Below[N=1,0,0,1]	0	0	0	0
ALT,Unknown, Month 24,Normal[N=1,0,0,1]	1	0	0	1
ALT,Unknown, Month 24,Above[N=1,0,0,1]	0	0	0	0
ALT,Unknown, Month 24,Unknown[N=1,0,0,1]	0	0	0	0
ALT,Normal, Month 24,Below [N=46,16,42,13]	0	0	0	0
ALT,Normal, Month 24,Normal[N=46,16,42,13]	46	16	40	13
ALT,Normal, Month 24,Above[N=46,16,42,13]	0	0	0	0
ALT,Normal, Month 24,Unknown[N=46,16,42,13]	0	0	2	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST) in Study Phase A

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST) in Study Phase A[103][104]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for AST for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 21 and 42 and Months 6, 12 and 24

Notes:

[103] - 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.
[104] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	17	49	18
Units: Subjects				
AST,Unknown,Day 21,Below [N=1,0,0,1]	0	0	0	0
AST,Unknown,Day 21,Normal [N=1,0,0,1]	1	0	0	1
AST,Unknown,Day 21,Above [N=1,0,0,1]	0	0	0	0
AST,Unknown,Day 21,Unknown [N=1,0,0,1]	0	0	0	0
AST,Normal,Day 21,Below [N=44,17,48,17]	0	0	0	0
AST,Normal,Day 21,Normal [N=44,17,48,17]	39	16	44	16
AST,Normal,Day 21,Above [N=44,17,48,17]	4	0	0	0
AST,Normal,Day21,Unknown [N=44, 17, 48, 17]	1	1	4	1
AST,Above,Day 21,Below [N=4,0,0,0]	0	0	0	0
AST,Above,Day 21,Normal [N=4,0,0,0]	2	0	0	0
AST,Above,Day 21,Above [N=4,0,0,0]	2	0	0	0
AST,Above,Day 21,Unknown [N=4,0,0,0]	0	0	0	0
AST,Unknown,Day 42,Below [N=1,0,0,1]	0	0	0	0

AST,Unknown,Day 42,Normal [N=1,0,0,1]	1	0	0	1
AST,Unknown,Day 42,Above [N=1,0,0,1]	0	0	0	0
AST,Unknown,Day 42,Unknown [N=1,0,0,1]	0	0	0	0
AST,Normal,Day 42,Below [N=45,17,49,17]	0	0	0	0
AST,Normal,Day 42,Normal [N=45,17,49,17]	42	13	45	15
AST,Normal,Day 42,Above [N=45,17,49,17]	2	2	0	0
AST,Normal,Day 42,Unknown [N=45,17,49,17]	1	2	4	2
AST,Above,Day 42,Below [N=4,0,0,0]	0	0	0	0
AST,Above,Day 42,Normal [N=4,0,0,0]	3	0	0	0
AST,Above,Day 42,Above [N=4,0,0,0]	1	0	0	0
AST,Above,Day 42,Unknown [N=4,0,0,0]	0	0	0	0
AST,Unknown, Month 6,Below [N=1,0,0,1]	0	0	0	0
AST,Unknown, Month 6,Normal [N=1,0,0,1]	1	0	0	1
AST,Unknown, Month 6,Above [N=1,0,0,1]	0	0	0	0
AST,Unknown, Month 6,Unknown [N=1,0,0,1]	0	0	0	0
AST,Normal, Month 6,Below [N=45,17,47,16]	0	0	0	0
AST,Normal, Month 6,Normal [N=45,17,47,16]	42	14	42	16
AST,Normal, Month 6,Above [N=45,17,47,16]	2	1	1	0
AST,Normal, Month 6,Unknown [N=45,17,47,16]	1	2	4	0
AST,Above, Month 6,Below [N=4,0,0,0]	0	0	0	0
AST,Above,Month 6,Normal [N=4,0,0,0]	3	0	0	0
AST,Above, Month 6,Above [N=4,0,0,0]	1	0	0	0
AST,Above, Month 6,Unknown [N=4,0,0,0]	0	0	0	0
AST,Unknown, Month 12,Below [N=1,0,0,1]	0	0	0	0
AST,Unknown, Month 12,Normal[N=1,0,0,1]	1	0	0	1
AST,Unknown, Month 12,Above[N=1,0,0,1]	0	0	0	0
AST,Unknown, Month 12,Unknown [N=1,0,0,1]	0	0	0	0
AST,Normal, Month 12,Below [N=45,17,44,16]	0	0	0	0
AST,Normal, Month 12,Normal[N=45,17,44,16]	41	16	42	16
AST,Normal, Month 12,Above[N=45,17,44,16]	2	1	0	0
AST,Normal, Month 12,Unknown[N=45,17,44,16]	2	0	2	0
AST,Above, Month 12,Below [N=4,0,0,0]	0	0	0	0
AST,Above, Month 12,Normal[N=4,0,0,0]	1	0	0	0

AST,Above, Month 12,Above [N=4,0,0,0]	2	0	0	0
AST,Above, Month 12,Unknown[N=4,0,0,0]	1	0	0	0
AST,Unknown, Month 24,Below [N=1,0,0,1]	0	0	0	0
AST,Unknown, Month 24,Normal [N=1,0,0,1]	1	0	0	1
AST,Unknown, Month 24,Above[N=1,0,0,1]	0	0	0	0
AST,Unknown, Month 24,Unknown [N=1,0,0,1]	0	0	0	0
AST,Normal,Month 24,Below [N=43,16,42,13]	0	0	0	0
AST,Normal,Month 24,Normal [N=43,16,42,13]	41	16	40	13
AST,Normal,Month 24,Above [N=43,16,42,13]	2	0	0	0
AST,Normal,Month 24,Unknown [N=43,16,42,13]	0	0	2	0
AST,Above,Month 24,Below [N=3,0,0,0]	0	0	0	0
AST,Above,Month 24,Normal [N=3,0,0,0]	2	0	0	0
AST,Above,Month 24,Above [N=3,0,0,0]	1	0	0	0
AST,Above,Month 24,Unknown [N=3,0,0,0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN) in Study Phase A

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN) in Study Phase A[105][106]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for BUN for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 21 and 42 and Months 6, 12 and 24

Notes:

[105] - 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.
[106] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	17	49	18
Units: Subjects				
BUN,Unknown, Day 21, Below [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Day 21, Normal [N=1,0,0,1]	1	0	0	0
BUN,Unknown, Day 21, Above [N=1,0,0,1]	0	0	0	1
BUN,Unknown, Day 21, Unknown [N=1,0,0,1]	0	0	0	0
BUN,Normal, Day 21, Below [N=46,17,47,16]	0	1	0	0
BUN,Normal, Day 21, Normal [N=46,17,47,16]	43	14	38	16
BUN,Normal, Day 21, Above [N=46,17,47,16]	2	1	5	0
BUN,Normal, Day 21, Unknown [N=46,17,47,16]	1	1	4	0
BUN,Above, Day 21, Below [N=2,0,1,1]	0	0	0	0
BUN,Above, Day 21, Normal [N=2,0,1,1]	1	0	1	0
BUN,Above, Day 21, Above [N=2,0,1,1]	1	0	0	1
BUN,Above, Day 21, Unknown [N=2,0,1,1]	0	0	0	0
BUN,Unknown, Day 42, Below [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Day 42, Normal [N=1,0,0,1]	1	0	0	1
BUN,Unknown, Day 42, Above [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Day 42, Unknown [N=1,0,0,1]	0	0	0	0
BUN,Normal, Day 42, Below [N=47,17,48,16]	0	0	0	0
BUN,Normal, Day 42, Normal [N=47,17,48,16]	40	16	38	12
BUN,Normal, Day 42,Above [N=47,17,48,16]	6	0	6	2
BUN,Normal, Day 42, Unknown [N=47,17,48,16]	1	1	4	2
BUN,Above, Day 42, Below [N=2,0,1,1]	0	0	0	0
BUN,Above, Day 42, Normal [N=2,0,1,1]	1	0	1	1
BUN,Above, Day 42, Above [N=2,0,1,1]	1	0	0	0
BUN,Above, Day 42, Unknkwn [N=2,0,1,1]	0	0	0	0
BUN,Unknown, Month 6,Below [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Month 6,Normal [N=1,0,0,1]	1	0	0	1
BUN,Unknown, Month 6,Above [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Month 6,Unknown [N=1,0,0,1]	0	0	0	0
BUN,Normal, Month 6,Below [N=47,17,46,15]	0	1	0	0

BUN,Normal, Month 6,Normal [N=47,17,46,15]	43	13	38	14
BUN,Normal, Month 6,Above [N=47,17,46,15]	3	1	4	1
BUN,Normal, Month 6,Unknown [N=47,17,46,15]	1	2	4	0
BUN,Above, Month 6,Below [N=2,0,1,1]	0	0	0	0
BUN,Above,Month 6,Normal [N=2,0,1,1]	2	0	1	0
BUN,Above, Month 6,Above [N=2,0,1,1]	0	0	0	1
BUN,Above, Month 6,Unknown [N=2,0,1,1]	0	0	0	0
BUN,Unknown, Month 12,Below [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Month 12,Normal[N=1,0,0,1]	1	0	0	1
BUN,Unknown, Month 12,Above [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Month 12,Unknown [N=1,0,0,1]	0	0	0	0
BUN,Normal, Month 12,Below [N=47,17,43,15]	0	0	1	0
BUN,Normal, Month 12,Normal [N=47,17,43,15]	41	16	40	13
BUN,Normal, Month 12,Above [N=47,17,43,15]	3	1	0	2
BUN,Normal, Month 12,Unknown [N=47,17,43,15]	3	0	2	0
BUN,Above, Month 12,Below [N=2,0,1,1]	0	0	0	0
BUN,Above, Month 12,Normal [N=2,0,1,1]	0	0	1	1
BUN,Above, Month 12,Above [N=2,0,1,1]	2	0	0	0
BUN,Above, Month 12,Unknown [N=2,0,1,1]	0	0	0	0
BUN,Unknown, Month 24,Below [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Month 24,Normal [N=1,0,0,1]	1	0	0	1
BUN,Unknown, Month 24,Above [N=1,0,0,1]	0	0	0	0
BUN,Unknown, Month 24,Unknown [N=1,0,0,1]	0	0	0	0
BUN,Normal, Month 24,Below [N=44,16,41,12]	0	0	1	0
BUN,Normal, Month 24,Normal [N=44,16,41,12]	42	16	37	11
BUN,Normal, Month 24,Above [N=44,16,41,12]	2	0	1	1
BUN,Normal, Month 24,Unknown [N=44,16,41,12]	0	0	2	0
BUN,Above, Month 24,Below [N=2,0,1,1]	0	0	0	0
BUN,Above, Month 24,Normal [N=2,0,1,1]	2	0	1	0
BUN,Above, Month 24,Above [N=2,0,1,1]	0	0	0	1
BUN,Above, Month 24,Unknown [N=2,0,1,1]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Creatine Phosphokinase (CPK) in Study Phase A

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Creatine Phosphokinase (CPK) in Study Phase A[107][108]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for CPK for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 21 and 42 and Months 6, 12 and 24

Notes:

[107] - 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.
[108] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to Creatine Phosphokinase (CPK)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	17	49	18
Units: Subjects				
CPK,Unknown, Day 21,Below [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Day 21,Normal [N=1,0,0,1]	1	0	0	1
CPK,Unknown, Day 21,Above [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Day 21,Unknown [N=1,0,0,1]	0	0	0	0
CPK,Normal, Day 21, Below [N=47,16,48,17]	0	0	0	0
CPK,Normal, Day 21, Normal [N=47,16,48,17]	44	15	42	16
CPK,Normal, Day 21, Above [N=47,16,48,17]	2	0	2	1

CPK,Normal, Day 21, Unknown [N=47,16,48,17]	1	1	4	0
CPK, Above, Day 21, Below [N=1,1,0,0]	0	0	0	0
CPK, Above, Day 21, Normal [N=1,1,0,0]	1	1	0	0
CPK, Above, Day 21, Above [N=1,1,0,0]	0	0	0	0
CPK, Above, Day 21, Unknown[N=1,1,0,0]	0	0	0	0
CPK,Unknown, Day 42,Below [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Day 42,Normal [N=1,0,0,1]	1	0	0	1
CPK,Unknown, Day 42,Above [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Day 42,Unknown [N=1,0,0,1]	0	0	0	0
CPK,Normal, Day 42, Below [N=49,16,49,17]	0	0	0	0
CPK,Normal, Day 42, Normal [N=49,16,49,17]	46	14	42	14
CPK,Normal, Day 42, Above [N=49,16,49,17]	2	1	3	1
CPK,Normal, Day 42, Unknown [N=49,16,49,17]	1	1	4	2
CPK, Above, Day 42, Below [N=0,1,0,0]	0	0	0	0
CPK, Above, Day 42, Normal [N=0,1,0,0]	0	1	0	0
CPK, Above, Day 42, Above [N=0,1,0,0]	0	0	1	0
CPK, Above, Day 42, Unknown [N=0,1,0,0]	0	0	0	0
CPK,Unknown, Month 6,Below [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Month 6,Normal [N=1,0,0,1]	1	0	0	1
CPK,Unknown, Month 6,Above [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Month 6,Unknown [N=1,0,0,1]	0	0	0	0
CPK,Normal, Month 6,Below [N=48,16,47,16]	0	0	0	0
CPK,Normal, Month 6,Normal [N=48,16,47,16]	45	13	38	15
CPK,Normal, Month 6,Above [N=48,16,47,16]	2	1	5	1
CPK,Normal, Month 6,Unknown [N=48,16,47,16]	1	2	4	0
CPK,Above, Month 6,Below [N=1,1,0,0]	0	0	0	0
CPK,Above,Month 6,Normal [N=1,1,0,0]	1	1	0	0
CPK,Above, Month 6,Above [N=1,1,0,0]	0	0	0	0
CPK,Above, Month 6,Unknown [N=1,1,0,0]	0	0	0	0
CPK,Unknown, Month 12,Below [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Month 12,Normal [N=1,0,0,1]	1	0	0	1
CPK,Unknown, Month 12,Above [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Month 12,Unknown [N=1,0,0,1]	0	0	0	0
CPK,Normal, Month 12,Below [N=48,16,44,16]	0	0	0	0

CPK,Normal, Month 12,Normal [N=48,16,44,16]	43	14	40	15
CPK,Normal, Month 12,Above [N=48,16,44,16]	2	2	2	1
CPK,Normal, Month 12,Unknown [N=48,16,44,16]	3	0	2	0
CPK,Above, Month 12,Below [N=1,1,0,0]	0	0	0	0
CPK,Above, Month 12,Normal [N=1,1,0,0]	1	1	0	0
CPK,Above, Month 12,Above [N=1,1,0,0]	0	0	0	0
CPK,Above, Month 12,Unknown [N=1,1,0,0]	0	0	0	0
CPK,Unknown, Month 24,Below [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Month 24,Normal [N=1,0,0,1]	1	0	0	1
CPK,Unknown, Month 24,Above [N=1,0,0,1]	0	0	0	0
CPK,Unknown, Month 24,Unknown [N=1,0,0,1]	0	0	0	0
CPK,Normal, Month 24,Below [N=45,15,41,13]	0	0	0	0
CPK,Normal, Month 24,Normal [N=45,15,41,13]	45	14	36	12
CPK,Normal, Month 24,Above [N=45,15,41,13]	0	1	2	1
CPK,Normal, Month 24,Unknown [N=45,15,41,13]	0	0	3	0
CPK,Above, Month 24,Below [N=1,1,1,0]	0	0	0	0
CPK,Above, Month 24,Normal [N=1,1,1,0]	1	1	0	0
CPK,Above, Month 24,Above [N=1,1,1,0]	0	0	1	0
CPK,Above, Month 24,Unknown [N=1,1,1,0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA) in Study Phase A

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA) in Study Phase A[109][110]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for CREA for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 21 and 42 and Months 6, 12 and 24

Notes:

[109] - 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.
[110] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	17	49	18
Units: Subjects				
CREA, Unknown, Day 21, Below [N=1,0,0,1]	0	0	0	0
CREA, Unknown, Day 21, Normal [N=1,0,0,1]	1	0	0	1
CREA, Unknown, Day 21, Above [N=1,0,0,1]	0	0	0	0
CREA, Unknown, Day 21, Unknown [N=1,0,0,1]	0	0	0	0
CREA, Normal, Day 21, Below [N=48,17,48,17]	0	0	0	0
CREA, Normal, Day 21, Normal [N=48,17,48,17]	47	16	42	17
CREA, Normal, Day 21, Above [N=48,17,48,17]	0	0	2	0
CREA, Normal, Day 21, Unknown [N=48,17,48,17]	1	1	4	0
CREA, Unknown, Day 42, Below [N=1,0,0,1]	0	0	0	0
CREA, Unknown, Day 42, Normal [N=1,0,0,1]	1	0	0	1
CREA, Unknown, Day 42, Above [N=1,0,0,1]	0	0	0	0
CREA, Unknown, Day 42, Unknown [N=1,0,0,1]	0	0	0	0
CREA, Normal, Day 42, Below [N=49,17,49,17]	0	0	0	0
CREA, Normal, Day 42, Normal [N=49,17,49,17]	48	16	43	15
CREA, Normal, Day 42, Above [N=49,17,49,17]	0	0	2	0
CREA, Normal, Day 42, Unknown [N=49,17,49,17]	1	1	4	2
CREA,Unknown, Month 6,Below [N=1,0,0,1]	0	0	0	0
CREA,Unknown, Month 6,Normal [N=1,0,0,1]	1	0	0	1
CREA,Unknown, Month 6,Above [N=1,0,0,1]	0	0	0	0
CREA,Unknown, Month 6,Unknown [N=1,0,0,1]	0	0	0	0
CREA,Normal, Month 6,Below [N=49,17,47,16]	0	0	0	0

CREA,Normal, Month 6,Normal [N=49,17,47,16]	48	15	43	16
CREA,Normal, Month 6,Above [N=49,17,47,16]	0	0	0	0
CREA,Normal, Month 6,Unknown [N=49,17,47,16]	1	2	4	0
CREA,Unknown, Month 12,Below [N=1,0,0,1]	0	0	0	0
CREA,Unknown, Month 12,Normal [N=1,0,0,1]	1	0	0	1
CREA,Unknown, Month 12,Above [N=1,0,0,1]	0	0	0	0
CREA,Unknown, Month 12,Unknown [N=1,0,0,1]	0	0	0	0
CREA,Normal, Month 12,Below [N=49,17,44,16]	0	0	0	0
CREA,Normal, Month 12,Normal [N=49,17,44,16]	46	17	42	16
CREA,Normal, Month 12,Above [N=49,17,44,16]	0	0	0	0
CREA,Normal, Month 12,Unknown [N=49,17,44,16]	3	0	2	0
CREA,Unknown, Month 24,Below [N=1,0,0,1]	0	0	0	0
CREA,Unknown, Month 24,Normal [N=1,0,0,1]	1	0	0	1
CREA,Unknown, Month 24,Above [N=1,0,0,1]	0	0	0	0
CREA,Unknown, Month 24,Unknown [N=1,0,0,1]	0	0	0	0
CREA,Normal, Month 24,Below [N=46,16,42,13]	0	0	0	0
CREA,Normal, Month 24,Normal [N=46,16,42,13]	46	16	39	13
CREA,Normal, Month 24,Above [N=46,16,42,13]	0	0	1	0
CREA,Normal, Month 24,Unknown [N=46,16,42,13]	0	0	2	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Lactate Dehydrogenase (LDH) in Study Phase A

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Lactate Dehydrogenase (LDH) in Study Phase A[111][112]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for LDH for subjects participating in Phase A of the study

End point type	Primary

End point timeframe:

At Days 21 and 42 and Months 6, 12 and 24

Notes:

[111] - 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.
[112] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Lactate Dehydrogenase (LDH)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	17	49	18
Units: Subjects				
LDH, Unknown, Day 21, Below [N=1,0,0,1]	0	0	0	0
LDH, Unknown, Day 21, Normal [N=1,0,0,1]	1	0	0	1
LDH, Unknown, Day 21, Above [N=1,0,0,1]	0	0	0	0
LDH, Unknown, Day 21, Unknown [N=1,0,0,1]	0	0	0	0
LDH, Normal, Day 21, Below [N=39,12,47,17]	0	0	0	0
LDH, Normal, Day 21, Normal [N=39,12,47,17]	36	8	40	14
LDH, Normal, Day 21, Above [N=39,12,47,17]	2	3	3	2
LDH, Normal, Day 21, Unknown [N=39,12,47,17]	1	1	4	1
LDH, Above, Day 21, Below [N=9,5,1,0]	0	0	0	0
LDH, Above, Day 21, Normal [N=9,5,1,0]	5	2	1	0
LDH, Above, Day 21, Above [N=9,5,1,0]	4	3	0	0
LDH, Above, Day 21, Unknown [N=9,5,1,0]	0	0	0	0
LDH, Unknown, Day 42, Below [N=1,0,0,1]	0	0	0	0
LDH, Unknown, Day 42, Normal [N=1,0,0,1]	1	0	0	1
LDH, Unknown, Day 42, Above [N=1,0,0,1]	0	0	0	0
LDH, Unknown, Day 42, Unknown [N=1,0,0,1]	0	0	0	0
LDH, Normal, Day 42, Above [N=40,12,48,17]	7	4	4	1
LDH, Normal, Day 42, Below [N=40,12,48,17]	0	0	0	0
LDH, Normal, Day 42, Normal [N=40,12,48,17]	32	6	41	14
LDH, Normal, Day 42, Unknown [N=40,12,48,17]	1	2	3	2
LDH, Above, Day 42, Above [N=9,5,1,0]	4	2	0	0
LDH, Above, Day 42, Below [N=9,5,1,0]	0	0	1	0

LDH, Above, Day 42, Normal [N=9,5,1,0]	5	3	0	0
LDH, Above, Day 42, Unknow [N=9,5,1,0]	0	0	0	0
LDH,Unknown, Month 6,Below [N=1,0,0,1]	0	0	0	0
LDH,Unknown, Month 6,Normal [N=1,0,0,1]	1	0	0	1
LDH,Unknown, Month 6,Above [N=1,0,0,1]	0	0	0	0
LDH,Unknown, Month 6,Unknown [N=1,0,0,1]	0	0	0	0
LDH,Normal, Month 6,Below [N=40,12,46,16]	0	0	0	0
LDH,Normal, Month 6,Normal [N=40,12,46,16]	31	7	38	13
LDH,Normal, Month 6,Above [N=40,12,46,16]	8	3	4	3
LDH,Normal, Month 6,Unknown [N=40,12,46,16]	1	2	4	0
LDH,Above, Month 6,Below [N=9,5,1,0]	0	0	0	0
LDH,Above,Month 6,Normal [N=9,5,1,0]	5	4	1	0
LDH,Above, Month 6,Above [N=9,5,1,0]	4	1	0	0
LDH,Above, Month 6,Unknown [N=9,5,1,0]	0	0	0	0
LDH,Unknown, Month 12,Below [N=1,0,0,1]	0	0	0	0
LDH,Unknown, Month 12,Normal [N=1,0,0,1]	1	0	0	1
LDH,Unknown, Month 12,Above [N=1,0,0,1]	0	0	0	0
LDH,Unknown, Month 12,Unknown [N=1,0,0,1]	0	0	0	0
LDH,Normal, Month 12,Below [N=40,12,43,16]	0	0	0	0
LDH,Normal, Month 12,Normal [N=40,12,43,16]	33	8	40	14
LDH,Normal, Month 12,Above [N=40,12,43,16]	4	4	1	2
LDH,Normal, Month 12,Unknown [N=40,12,43,16]	3	0	2	0
LDH,Above, Month 12,Below [N=9,5,1,0]	0	0	0	0
LDH,Above, Month 12,Normal [N=9,5,1,0]	6	4	1	0
LDH,Above, Month 12,Above [N=9,5,1,0]	3	1	0	0
LDH,Above, Month 12,Unknown [N=9,5,1,0]	0	0	0	0
LDH,Unknown, Month 24,Below [N=1,0,0,1]	0	0	0	0
LDH,Unknown, Month 24,Normal [N=1,0,0,1]	1	0	0	1
LDH,Unknown, Month 24,Above [N=1,0,0,1]	0	0	0	0
LDH,Unknown, Month 24,Unknown [N=1,0,0,1]	0	0	0	0
LDH,Normal, Month 24,Below [N=38,11,42,13]	0	0	0	0
LDH,Normal, Month 24,Normal [N=38,11,42,13]	35	8	36	11

LDH,Normal, Month 24,Above [N=38,11,42,13]	3	3	3	2
LDH,Normal, Month 24,Unknown [N=38,11,42,13]	0	0	3	0
LDH,Above, Month 24,Below [N=8,5,0,0]	0	0	0	0
LDH,Above, Month 24,Normal [N=8,5,0,0]	6	5	0	0
LDH,Above, Month 24,Above [N=8,5,0,0]	2	0	0	0
LDH,Above, Month 24,Unknown [N=8,5,0,0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT) for Subjects in Study Phase B

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT) for Subjects in Study Phase B[113][114]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for ALT for subjects participating in Phase B of the study.

End point type	Primary

End point timeframe:

At Days 21 and 42 and Months 6, 12 and 24

Notes:

[113] - 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.
[114] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	16	46	16
Units: Subjects				
ALT,Unknown,Day 21,Below [N=0,1,1,0]	0	0	0	0
ALT,Unknown,Day 21,Normal [N=0,1,1,0]	0	0	1	0
ALT,Unknown,Day 21,Above [N=0,1,1,0]	0	1	0	0

ALT,Unknown,Day 21,Unknown [N=0,1,1,0]	0	0	0	0
ALT,Normal,Day 21,Below [N=48,16,45,16]	0	0	0	0
ALT,Normal,Day 21,Normal [N=48,16,45,16]	44	16	44	16
ALT,Normal,Day 21,Above [N=48,16,45,16]	1	0	1	0
ALT,Normal,Day 21,Unknown [N=48,16,45,16]	3	0	0	0
ALT,Above,Day 21,Below [N=0,0,0,1]	0	0	0	0
ALT,Above,Day 21,Normal [N=0,0,0,1]	0	0	0	1
ALT,Above,Day 21,Above [N=0,0,0,1]	0	0	0	0
ALT,Above,Day 21,Unknown [N=0,0,0,1]	0	0	0	0
ALT,Unknown,Day 42,Below [N=0,1,1,0]	0	0	0	0
ALT,Unknown,Day 42,Normal [N=0,1,1,0]	0	1	1	0
ALT,Unknown,Day 42,Above [N=0,1,1,0]	0	0	0	0
ALT,Unknown,Day 42,Unknown [N=0,1,1,0]	0	0	0	0
ALT,Normal,Day 42,Below [N=49,16,46,16]	0	0	0	0
ALT,Normal,Day 42,Normal [N=49,16,46,16]	46	16	44	16
ALT,Normal,Day 42,Above [N=49,16,46,16]	1	0	2	0
ALT,Normal,Day 42,Unknown [N=49,16,46,16]	2	0	0	0
ALT,Above,Day 42,Below [N=0,0,0,1]	0	0	0	0
ALT,Above,Day 42,Normal [N=0,0,0,1]	0	0	0	0
ALT,Above,Day 42,Above [N=0,0,0,1]	0	0	0	1
ALT,Above,Day 42,Unknown [N=0,0,0,1]	0	0	0	0
ALT,Unknown,Month 6,Below [N=0,1,1,0]	0	0	0	0
ALT,Unknown,Month 6,Normal [N=0,1,1,0]	0	1	1	0
ALT,Unknown,Month 6,Above [N=0,1,1,0]	0	0	0	0
ALT,Unknown,Month 6,Unknown [N=0,1,1,0]	0	0	0	0
ALT,Normal,Month 6,Below [N=49,16,44,16]	0	0	0	0
ALT,Normal,Month 6,Normal [N=49,16,44,16]	48	16	44	16
ALT,Normal,Month 6,Above [N=49,16,44,16]	0	0	0	0
ALT,Normal,Month 6,Unknown [N=49,16,44,16]	1	0	0	0
ALT,Above,Month 6,Below [N=0,0,0,1]	0	0	0	0
ALT,Above,Month 6,Normal [N=0,0,0,1]	0	0	0	1
ALT,Above, Month 6,Above [N=0,0,0,1]	0	0	0	0
ALT,Above, Month 6,Unknown [N=0,0,0,1]	0	0	0	0
ALT,Unknown, Month 12,Below [N=0,1,1,0]	0	0	0	0

ALT,Unknown, Month 12,Normal [N=0,1,1,0]	0	1	1	0
ALT,Unknown, Month 12,Above [N=0,1,1,0]	0	0	0	0
ALT,Unknown, Month 12,Unknown [N=0,1,1,0]	0	0	0	0
ALT,Normal, Month 12,Below [N=46,16,44,16]	0	0	0	0
ALT,Normal, Month 12,Normal [N=46,16,44,16]	44	16	44	16
ALT,Normal, Month 12,Above [N=46,16,44,16]	0	0	0	0
ALT,Normal, Month 12,Unknown [N=46,16,44,16]	2	0	0	0
ALT,Above, Month 12,Below [N=0,0,0,1]	0	0	0	0
ALT,Above,Month 12,Normal [N=0,0,0,1]	0	0	0	1
ALT,Above, Month 12,Above [N=0,0,0,1]	0	0	0	0
ALT,Above, Month 12,Unknown [N=0,0,0,1]	0	0	0	0
ALT,Unknown, Month 24,Below [N=0,1,0,0]	0	0	0	0
ALT,Unknown, Month 24,Normal [N=0,1,0,0]	0	1	0	0
ALT,Unknown, Month 24,Above [N=0,1,0,0]	0	0	0	0
ALT,Unknown, Month 24,Unknown [N=0,1,0,0]	0	0	0	0
ALT,Normal, Month 24,Below [N=45,16,44,16]	0	0	0	0
ALT,Normal, Month 24,Normal [N=45,16,44,16]	44	16	43	16
ALT,Normal, Month 24,Above [N=45,16,44,16]	1	0	1	0
ALT,Normal, Month 24,Unknown [N=45,16,44,16]	0	0	0	0
ALT,Above, Month 24,Below [N=0,0,0,1]	0	0	0	0
ALT,Above, Month 24,Normal [N=0,0,0,1]	0	0	0	1
ALT,Above, Month 24,Above [N=0,0,0,1]	0	0	0	0
ALT,Above, Month 24,Unknown [N=0,0,0,1]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST) in Study Phase B

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST) in Study Phase B[115][116]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled

post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for AST for subjects participating in Phase B of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[115] - 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.
[116] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	15	43	16
Units: Subjects				
AST,Unknown,Day 21,Below [N=0,1,1,0]	0	0	0	0
AST,Unknown,Day 21,Normal [N=0,1,1,0]	0	0	1	0
AST,Unknown,Day 21,Above [N=0,1,1,0]	0	1	0	0
AST,Unknown,Day 21,Unknown [N=0,1,1,0]	0	0	0	0
AST,Normal,Day 21,Below [N=46,15,42,16]	0	0	0	0
AST,Normal,Day 21,Normal [N=46,15,42,16]	40	15	41	16
AST,Normal,Day 21,Above [N=46,15,42,16]	3	0	1	0
AST,Normal,Day 21,Unknown [N=46,15,42,16]	3	0	0	0
AST,Above,Day 21,Below [N=2,1,3,1]	0	0	0	0
AST,Above,Day 21,Normal [N=2,1,3,1]	1	1	3	1
AST,Above,Day 21,Above [N=2,1,3,1]	0	0	0	0
AST,Above,Day 21,Unknown [N=2,1,3,1]	1	0	0	0
AST,Unknown,Day 42,Below [N=0,1,1,0]	0	0	0	0
AST,Unknown,Day 42,Normal [N=0,1,1,0]	0	1	1	0
AST,Unknown,Day 42,Above [N=0,1,1,0]	0	0	0	0
AST,Unknown,Day 42,Unknown [N=0,1,1,0]	0	0	0	0
AST,Normal,Day 42,Below [N=47,15,43,16]	0	0	0	0
AST,Normal,Day 42,Normal [N=47,15,43,16]	40	13	40	16

AST,Normal,Day 42,Above [N=47,15,43,16]	5	2	3	0
AST,Normal,Day 42,Unknown [N=47,15,43,16]	2	0	0	0
AST,Above,Day 42,Below [N=2,1,3,1]	0	0	0	0
AST,Above,Day 42,Normal [N=2,1,3,1]	2	1	3	0
AST,Above,Day 42,Above [N=2,1,3,1]	0	0	0	1
AST,Above,Day 42,Unknown [N=2,1,3,1]	0	0	0	0
AST,Unknown, Month 6,Below [N=0,1,1,0]	0	0	0	0
AST,Unknown, Month 6,Normal [N=0,1,1,0]	0	1	1	0
AST,Unknown, Month 6,Above [N=0,1,1,0]	0	0	0	0
AST,Unknown, Month 6,Unknown [N=0,1,1,0]	0	0	0	0
AST,Normal, Month 6,Below [N=47,15,41,16]	0	0	0	0
AST,Normal, Month 6,Normal [N=47,15,41,16]	45	14	40	16
AST,Normal, Month 6,Above [N=47,15,41,16]	2	1	0	0
AST,Normal, Month 6,Unknown [N=47,15,41,16]	0	0	1	0
AST,Above, Month 6,Below [N=2,1,3,1]	0	0	0	0
AST,Above,Month 6,Normal [N=2,1,3,1]	2	1	3	1
AST,Above, Month 6,Above [N=2,1,3,1]	0	0	0	0
AST,Above, Month 6,Unknown [N=2,1,3,1]	0	0	0	0
AST,Unknown, Month 12,Below [N=0,1,1,0]	0	0	0	0
AST,Unknown, Month 12,Normal [N=0,1,1,0]	0	1	1	0
AST,Unknown, Month 12,Above [N=0,1,1,0]	0	0	0	0
AST,Unknown, Month 12,Unknown [N=0,1,1,0]	0	0	0	0
AST,Normal, Month 12,Below [N=45,15,41,16]	0	0	0	0
AST,Normal, Month 12,Normal [N=45,15,41,16]	44	15	41	16
AST,Normal, Month 12,Above [N=45,15,41,16]	0	0	0	0
AST,Normal, Month 12,Unknown [N=45,15,41,16]	1	0	0	0
AST,Above, Month 12,Below [N=1,1,3,1]	0	0	0	0
AST,Above,Month 12,Normal [N=1,1,3,1]	0	1	3	1
AST,Above, Month 12,Above [N=1,1,3,1]	0	0	0	0
AST,Above, Month 12,Unknown [N=1,1,3,1]	1	0	0	0
AST,Unknown, Month 24,Below [N=0,1,0,0]	0	0	0	0
AST,Unknown, Month 24,Normal [N=0,1,0,0]	0	1	0	0
AST,Unknown, Month 24,Above [N=0,1,0,0]	0	0	0	0

AST,Unknown, Month 24,Unknown [N=0,1,0,0]	0	0	0	0
AST,Normal, Month 24,Below [N=45,15,41,16]	0	0	0	0
AST,Normal, Month 24,Normal [N=45,15,41,16]	44	15	41	16
AST,Normal, Month 24,Above [N=45,15,41,16]	1	0	0	0
AST,Normal, Month 24,Unknown [N=45,15,41,16]	0	0	0	0
AST,Above, Month 24,Below [N=0,1,3,1]	0	0	0	0
AST,Above, Month 24,Normal [N=0,1,3,1]	0	1	2	1
AST,Above, Month 24,Above [N=0,1,3,1]	0	0	1	0
AST,Above, Month 24,Unknown [N=0, 1, 3, 1]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN) in Study Phase B

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN) in Study Phase B[117][118]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for BUN for subjects participating in Phase B of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[117] - 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.
[118] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	17	47	17
Units: Subjects				
BUN,Unknown,Day 21,Below [N=0,1,1,1]	0	0	0	0
BUN,Unknown,Day 21,Normal [N=0,1,1,1]	0	0	1	1
BUN,Unknown,Day 21,Above [N=0,1,1,1]	0	1	0	0
BUN,Unknown,Day 21,Unknown [N=0,1,1,1]	0	0	0	0
BUN,Normal,Day 21,Below [N=44,14,40,13]	0	0	0	0
BUN,Normal,Day 21,Normal [N=44,14,40,13]	35	13	37	12
BUN,Normal,Day 21,Above [N=44,14,40,13]	6	1	3	1
BUN,Normal,Day 21,Unknown [N=44,14,40,13]	3	0	0	0
BUN,Above,Day 21,Below [N=4,2,5,3]	0	0	0	0
BUN,Above,Day 21,Normal [N=4,2,5,3]	3	1	5	2
BUN,Above,Day 21,Above [N=4,2,5,3]	1	1	0	1
BUN,Above,Day 21,Unknown [N=4,2,5,3]	0	0	0	0
BUN,Unknown,Day 42,Below [N=0,1,1,1]	0	0	0	0
BUN,Unknown,Day 42,Normal [N=0,1,1,1]	0	1	1	1
BUN,Unknown,Day 42,Above [N=0,1,1,1]	0	0	0	0
BUN,Unknown,Day 42,Unknown [N=0,1,1,1]	0	0	0	0
BUN,Normal,Day 42,Below [N=45,14,41,13]	0	0	0	0
BUN,Normal,Day 42,Normal [N=45,14,41,13]	38	12	39	11
BUN,Normal,Day 42,Above [N=45,14,41,13]	6	2	2	2
BUN,Normal,Day 42,Unknown [N=45,14,41,13]	1	0	0	0
BUN,Above,Day 42,Below [N=4,2,5,3]	0	0	0	0
BUN,Above,Day 42,Normal [N=4,2,5,3]	2	1	3	2
BUN,Above,Day 42,Above [N=4,2,5,3]	1	1	2	1
BUN,Above,Day 42,Unknown [N=4,2,5,3]	1	0	0	0
BUN,Unknown, Month 6,Below [N=0,1,1,1]	0	0	0	0
BUN,Unknown, Month 6,Normal [N=0,1,1,1]	0	1	1	1
BUN,Unknown, Month 6,Above [N=0,1,1,1]	0	0	0	0
BUN,Unknown, Month 6,Unknown [N=0,1,1,1]	0	0	0	0
BUN,Normal, Month 6,Below [N=45,14,39,13]	0	0	0	0
BUN,Normal, Month 6,Normal [N=45,14,39,13]	42	12	39	13

BUN,Normal, Month 6,Above [N=45,14,39,13]	3	2	0	0
BUN,Normal, Month 6,Unknown [N=45,14,39,13]	0	0	0	0
BUN,Above, Month 6,Below [N=4,2,5,3]	0	0	0	0
BUN,Above,Month 6,Normal [N=4,2,5,3]	4	1	5	3
BUN,Above, Month 6,Above [N=4,2,5,3]	0	1	0	0
BUN,Above, Month 6,Unknown [N=4,2,5,3]	0	0	0	0
BUN,Unknown, Month 12,Below [N=0,1,1,1]	0	0	0	0
BUN,Unknown, Month 12,Normal [N=0,1,1,1]	0	1	1	1
BUN,Unknown, Month 12,Above [N=0,1,1,1]	0	0	0	0
BUN,Unknown, Month 12,Unknown [N=0,1,1,1]	0	0	0	0
BUN,Normal, Month 12,Below [N=42,14,39,13]	0	0	0	0
BUN,Normal, Month 12,Normal [N=42,14,39,13]	36	12	38	11
BUN,Normal, Month 12,Above [N=42,14,39,13]	4	2	1	2
BUN,Normal, Month 12,Unknown [N=42,14,39,13]	2	0	0	0
BUN,Above, Month 12,Below [N=4,2,5,3]	0	0	0	0
BUN,Above,Month 12,Normal [N=4,2,5,3]	3	2	5	2
BUN,Above, Month 12,Above [N=4,2,5,3]	1	0	0	1
BUN,Above, Month 12,Unknown [N=4,2,5,3]	0	0	0	0
BUN,Unknown, Month 24,Below [N=0,1,0,1]	0	0	0	0
BUN,Unknown, Month 24,Normal [N=0,1,0,1]	0	1	0	1
BUN,Unknown, Month 24,Above [N=0,1,0,1]	0	0	0	0
BUN,Unknown, Month 24,Unknown [N=0,1,0,1]	0	0	0	0
BUN,Normal, Month 24,Below [N=41,14,39,13]	0	0	0	0
BUN,Normal, Month 24,Normal [N=41,14,39,13]	36	11	39	13
BUN,Normal, Month 24,Above [N=41,14,39,13]	5	3	0	0
BUN,Normal, Month 24,Unknown [N=41,14,39,13]	0	0	0	0
BUN,Above, Month 24,Below [N=4,2,5,3]	0	0	0	0
BUN,Above, Month 24,Normal [N=4,2,5,3]	4	1	2	2
BUN,Above, Month 24,Above [N=4,2,5,3]	0	1	3	1
BUN,Above, Month 24,Unknown [N=4,2,5,3]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Creatine Phosphokinase (CPK) in Study Phase B

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Creatine Phosphokinase (CPK) in Study Phase B[119][120]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for CPK for subjects participating in Phase B of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[119] - 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.
[120] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to Creatine Phosphokinase (CPK)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	17	47	17
Units: Subjects				
CPK,Unknown,Day 21,Below [N=0,1,1,0]	0	0	0	0
CPK,Unknown,Day 21,Normal [N=0,1,1,0]	0	1	1	0
CPK,Unknown,Day 21,Above [N=0,1,1,0]	0	0	0	0
CPK,Unknown,Day 21,Unknown [N=0,1,1,0]	0	0	0	0
CPK,Normal,Day 21,Below [N=46,16,43,16]	0	0	0	0
CPK,Normal,Day 21,Normal [N=46,16,43,16]	46	16	43	16
CPK,Normal,Day 21,Above [N=46,16,43,16]	2	1	0	0
CPK,Normal,Day 21,Unknown [N=46,16,43,16]	2	0	0	0
CPK,Above,Day 21,Below [N=2,0,2,1]	0	0	0	0
CPK,Above,Day 21,Normal [N=2,0,2,1]	0	0	1	0
CPK,Above,Day 21,Above [N=2,0,2,1]	1	0	1	1
CPK,Above,Day 21,Unknown [N=2,0,2,1]	1	0	0	1

CPK,Unknown,Day 42,Below [N=0,1,1,0]	0	0	0	0
CPK,Unknown,Day 42,Normal [N=0,1,1,0]	0	1	1	0
CPK,Unknown,Day 42,Above [N=0,1,1,0]	0	0	0	0
CPK,Unknown,Day 42,Unknown [N=0,1,1,0]	0	0	0	0
CPK,Normal,Day 42,Below [N=47,16,44,16]	0	0	0	0
CPK,Normal,Day 42,Normal [N=47,16,44,16]	43	16	42	14
CPK,Normal,Day 42,Above [N=47,16,44,16]	2	2	2	0
CPK,Normal,Day 42,Unknown [N=47,16,44,16]	2	0	0	0
CPK,Above,Day 42,Below [N=2,0,2,1]	0	0	0	0
CPK,Above,Day 42,Normal [N=2,0,2,1]	0	0	1	0
CPK,Above,Day 42,Above [N=2,0,2,1]	2	0	1	1
CPK,Above,Day 42,Unknown [N=2,0,2,1]	0	0	0	0
CPK,Unknown, Month 6,Below [N=0,1,1,0]	0	0	0	0
CPK,Unknown, Month 6,Normal [N=0,1,1,0]	0	1	0	0
CPK,Unknown, Month 6,Above [N=0,1,1,0]	0	0	1	0
CPK,Unknown, Month 6,Unknown [N=0,1,1,0]	0	0	0	0
CPK,Normal, Month 6,Below [N=47,16,43,16]	0	0	0	0
CPK,Normal, Month 6,Normal [N=47,16,43,16]	46	13	42	15
CPK,Normal, Month 6,Above [N=47,16,43,16]	1	3	1	1
CPK,Normal, Month 6,Unknown [N=47,16,43,16]	0	0	0	0
CPK,Above, Month 6,Below [N=2,0,1,1]	0	0	0	0
CPK,Above,Month 6,Normal [N=2,0,1,1]	1	0	1	0
CPK,Above, Month 6,Above [N=2,0,1,1]	1	0	0	1
CPK,Above, Month 6,Unknown [N=2,0,1,1]	0	0	0	0
CPK,Unknown, Month 12,Below [N=0,1,1,0]	0	0	0	0
CPK,Unknown, Month 12,Normal [N=0,1,1,0]	0	1	1	0
CPK,Unknown, Month 12,Above [N=0,1,1,0]	0	0	0	0
CPK,Unknown, Month 12,Unknown [N=0,1,1,0]	0	0	0	0
CPK,Normal, Month 12,Below [N=44,16,43,16]	0	0	0	0
CPK,Normal, Month 12,Normal [N=44,16,43,16]	39	13	42	16
CPK,Normal, Month 12,Above [N=44,16,43,16]	4	3	1	0
CPK,Normal, Month 12,Unknown [N=44,16,43,16]	1	0	0	0
CPK,Above, Month 12,Below [N=2,0,1,1]	0	0	0	0

CPK,Above,Month 12,Normal [N=2,0,1,1]	0	0	1	1
CPK,Above, Month 12,Above [N=2,0,1,1]	1	0	0	0
CPK,Above, Month 12,Unknown [N=2,0,1,1]	1	0	0	0
CPK,Unknown, Month 24,Below [N=0,1,0,0]	0	0	0	0
CPK,Unknown, Month 24,Normal [N=0,1,0,0]	0	1	0	0
CPK,Unknown, Month 24,Above [N=0,1,0,0]	0	0	0	0
CPK,Unknown, Month 24,Unknown [N=0,1,0,0]	0	0	0	0
CPK,Normal, Month 24,Below [N=44,16,43,16]	0	0	0	0
CPK,Normal, Month 24,Normal [N=44,16,43,16]	43	14	41	16
CPK,Normal, Month 24,Above [N=44,16,43,16]	1	2	2	0
CPK,Normal, Month 24,Unknown [N=44,16,43,16]	0	0	0	0
CPK,Above, Month 24,Below [N=1,0,1,1]	0	0	0	0
CPK,Above, Month 24,Normal [N=1,0,1,1]	1	0	1	0
CPK,Above, Month 24,Above [N=1,0,1,1]	0	0	0	1
CPK,Above, Month 24,Unknown [N=1,0,1,1]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA) in Study Phase B

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA) in Study Phase B[121][122]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for CREA for subjects participating in Phase B of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[121] - 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.

[122] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	17	46	16
Units: Subjects				
CREA,Unknown,Day 21,Below [N=0,1,1,0]	0	0	0	0
CREA,Unknown,Day 21,Normal [N=0,1,1,0]	0	1	1	0
CREA,Unknown,Day 21,Above [N=0,1,1,0]	0	0	0	0
CREA,Unknown,Day 21,Unknown [N=0,1,1,0]	0	0	0	0
CREA,Normal,Day 21,Below [N=48,16,44,17]	0	0	0	0
CREA,Normal,Day 21,Normal [N=48,16,44,17]	44	16	43	17
CREA,Normal,Day 21,Above [N=48,16,44,17]	1	0	1	0
CREA,Normal,Day 21,Unknown [N=48,16,44,17]	3	0	0	0
CREA,Above,Day 21,Below [N=0,0,1,0]	0	0	0	0
CREA,Above,Day 21,Normal [N=0,0,1,0]	0	0	1	0
CREA,Above,Day 21,Above [N=0,0,1,0]	0	0	0	0
CREA,Above,Day 21,Unknow [N=0,0,1,0]	0	0	0	0
CREA,Unknown,Day 42,Below [N=0,1,1,0]	0	0	0	0
CREA,Unknown,Day 42,Normal [N=0,1,1,0]	0	1	1	0
CREA,Unknown,Day 42,Above [N=0,1,1,0]	0	0	0	0
CREA,Unknown,Day 42,Unknown [N=0,1,1,0]	0	0	0	0
CREA,Normal,Day 42,Below [N=49,16,45,17]	0	0	0	0
CREA,Normal,Day 42,Normal [N=49,16,45,17]	46	16	45	17
CREA,Normal,Day 42,Above [N=49,16,45,17]	1	0	0	0
CREA,Normal,Day 42,Unknown [N=49,16,45,17]	2	0	0	0
CREA,Above,Day 42,Below [N=0,0,1,0]	0	0	0	0
CREA,Above,Day 42,Normal [N=0,0,1,0]	0	0	1	0
CREA,Above,Day 42,Above [N=0,0,1,0]	0	0	0	0
CREA,Above,Day 42,Unknown [N=0,0,1,0]	0	0	0	0
CREA,Unknown, Month 6,Below [N=0,1,1,0]	0	0	0	0
CREA,Unknown, Month 6,Normal [N=0,1,1,0]	0	1	1	0

CREA,Unknown, Month 6,Above [N=0,1,1,0]	0	0	0	0
CREA,Unknown, Month 6,Unknown [N=0,1,1,0]	0	0	0	0
CREA,Normal, Month 6,Below [N=49,16,43,17]	0	0	0	0
CREA,Normal, Month 6,Normal [N=49,16,43,17]	49	16	42	17
CREA,Normal, Month 6,Above [N=49,16,43,17]	0	0	1	0
CREA,Normal, Month 6,Unknown [N=49,16,43,17]	0	0	0	0
CREA,Above, Month 6,Below [N=0,0,1,0]	0	0	0	0
CREA,Above, Month 6,Normal [N=0,0,1,0]	0	0	0	0
CREA,Above, Month 6,Above [N=0,0,1,0]	0	0	1	0
CREA,Above, Month 6,Unknown [N=0,0,1,0]	0	0	0	0
CREA,Unknown, Month 12,Below [N=0,1,1,0]	0	0	0	0
CREA,Unknown, Month 12,Normal [N=0,1,1,0]	0	1	1	0
CREA,Unknown, Month 12,Above [N=0,1,1,0]	0	0	0	0
CREA,Unknown, Month 12,Unknown [N=0,1,1,0]	0	0	0	0
CREA,Normal, Month 12,Below [N=46,16,43,17]	0	0	0	0
CREA,Normal, Month 12,Normal [N=46,16,43,17]	44	16	42	17
CREA,Normal, Month 12,Above [N=44,16,43,17]	0	0	1	0
CREA,Normal, Month 12,Unknown [N=44,16,43,17]	2	0	0	0
CREA,Above, Month 12,Below [N=0,0,1,0]	0	0	0	0
CREA,Above,Month 12,Normal [N=0,0,1,0]	0	0	1	0
CREA,Above, Month 12,Above [N=0,0,1,0]	0	0	0	0
CREA,Above, Month 12,Unknown [N=0,0,1,0]	0	0	0	0
CREA,Unknown, Month 24,Below [N=0,1,0,0]	0	0	0	0
CREA,Unknown, Month 24,Normal [N=0,1,0,0]	0	1	0	0
CREA,Unknown, Month 24,Above [N=0,1,0,0]	0	0	0	0
CREA,Unknown, Month 24,Unknown [N=0,1,0,0]	0	0	0	0
CREA,Normal, Month 24,Below [N=45,16,43,17]	0	0	0	0
CREA,Normal, Month 24,Normal [N=45,16,43,17]	45	16	43	17
CREA,Normal, Month 24,Above [N=45,16,43,17]	0	0	0	0
CREA,Normal, Month 24,Unknown [N=45,16,43,17]	0	0	0	0
CREA,Above, Month 24,Below [N=0,0,1,0]	0	0	0	0

CREA,Above, Month 24,Normal [N=0,0,1,0]	0	0	1	0
CREA,Above, Month 24,Above [N=0,0,1,0]	0	0	0	0
CREA,Above, Month 24,Unknown [N=0,0,1,0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Lactate Dehydrogenase (LDH) in Study Phase B

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Lactate Dehydrogenase (LDH) in Study Phase B[123][124]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for LDH for subjects participating in Phase B of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[123] - 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.
[124] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Lactate Dehydrogenase (LDH)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	17	47	17
Units: Subjects				
LDH,Unknown,Day 21,Below [N=0,1,1,0]	0	0	0	0
LDH,Unknown,Day 21,Normal [N=0,1,1,0]	0	0	1	0
LDH,Unknown,Day 21,Above [N=0,1,1,0]	0	1	0	0
LDH,Unknown,Day 21,Unknown [N=0,1,1,0]	0	0	0	0
LDH,Normal,Day 21,Below [N=43,14,38,15]	0	0	0	0
LDH,Normal,Day 21,Normal [N=43,14,38,15]	33	13	38	15

LDH,Normal,Day 21,Above [N=43,14,38,15]	7	1	0	0
LDH,Normal,Day 21,Unknown [N=43,14,38,15]	3	0	0	0
LDH,Above,Day 21,Below [N=5,2,7,2]	0	0	0	0
LDH,Above,Day 21,Normal [N=5,2,7,2]	2	1	3	1
LDH,Above,Day 21,Above [N=5,2,7,2]	2	1	4	1
LDH,Above,Day 21,Unknown [N=5,2,7,2]	1	0	0	0
LDH,Unknown,Day 42,Below [N=0,1,1,0]	0	0	0	0
LDH,Unknown,Day 42,Normal [N=0,1,1,0]	0	0	1	0
LDH,Unknown,Day 42,Above [N=0,1,1,0]	0	1	0	0
LDH,Unknown,Day 42,Unknown [N=0,1,1,0]	0	0	0	0
LDH,Normal,Day 42,Below [N=44,14,39,15]	0	0	0	0
LDH,Normal,Day 42,Normal [N=44,14,39,15]	33	9	37	14
LDH,Normal,Day 42,Above [N=44,14,39,15]	9	5	2	1
LDH,Normal,Day 42,Unknown [N=44,14,39,15]	2	0	0	0
LDH,Above,Day 42,Below [N=5,2,7,2]	0	0	0	0
LDH,Above,Day 42,Normal [N=5,2,7,2]	2	1	3	0
LDH,Above,Day 42,Above [N=5,2,7,2]	3	1	4	2
LDH,Above,Day 42,Unknown [N=5,2,7,2]	0	0	0	0
LDH,Unknown, Month 6,Below [N=0,1,1,0]	0	0	0	0
LDH,Unknown, Month 6,Normal [N=0,1,1,0]	0	1	1	0
LDH,Unknown, Month 6,Above [N=0,1,1,0]	0	0	0	0
LDH,Unknown, Month 6,Unknown [N=0,1,1,0]	0	0	0	0
LDH,Normal, Month 6,Below [N=44,14,38,15]	0	0	0	0
LDH,Normal, Month 6,Normal [N=44,14,38,15]	37	9	34	14
LDH,Normal, Month 6,Above [N=44,14,38,15]	6	5	3	1
LDH,Normal, Month 6,Unknown [N=44,14,38,15]	1	0	1	0
LDH,Above, Month 6,Below [N=5,2,6,2]	0	0	0	0
LDH,Above,Month 6,Normal [N=5,2,6,2]	3	2	2	1
LDH,Above, Month 6,Above [N=5,2,6,2]	2	0	4	1
LDH,Above, Month 6,Unknown [N=5,2,6,2]	0	0	0	0
LDH,Unknown, Month 12,Below [N=0,1,1,0]	0	0	0	0
LDH,Unknown, Month 12,Normal [N=0,1,1,0]	0	0	1	0
LDH,Unknown, Month 12,Above [N=0,1,1,0]	0	1	0	0
LDH,Unknown, Month 12,Unknown [N=0,1,1,0]	0	0	0	0

LDH,Normal, Month 12,Below [N=42,14,38,15]	0	0	0	0
LDH,Normal, Month 12,Normal [N=42,14,38,15]	32	10	36	15
LDH,Normal, Month 12,Above [N=42,14,38,15]	9	4	2	0
LDH,Normal, Month 12,Unknown [N=42,14,38,15]	1	0	0	0
LDH,Above, Month 12,Below [N=4,2,6,2]	0	0	0	0
LDH,Above,Month 12,Normal [N=4,2,6,2]	3	2	5	1
LDH,Above, Month 12,Above [N=4,2,6,2]	0	0	1	1
LDH,Above, Month 12,Unknown [N=4,2,6,2]	1	0	0	0
LDH,Unknown, Month 24,Below [N=0,1,0,0]	0	0	0	0
LDH,Unknown, Month 24,Normal [N=0,1,0,0]	0	1	0	0
LDH,Unknown, Month 24,Above [N=0,1,0,0]	0	0	0	0
LDH,Unknown, Month 24,Unknown [N=0,1,0,0]	0	0	0	0
LDH,Normal, Month 24,Below [N=42,14,38,15]	0	0	0	0
LDH,Normal, Month 24,Normal [N=42,14,38,15]	40	13	37	15
LDH,Normal, Month 24,Above [N=42,14,38,15]	2	1	1	0
LDH,Normal, Month 24,Unknown [N=42,14,38,15]	0	0	0	0
LDH,Above, Month 24,Below [N=3,2,6,2]	0	0	0	0
LDH,Above, Month 24,Normal [N=3,2,6,2]	3	2	4	0
LDH,Above, Month 24,Above [N=3,2,6,2]	0	0	2	2
LDH,Above, Month 24,Unknown [N=3,2,6,2]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT) for Subjects in Study Phase C

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT) for Subjects in Study Phase C[125][126]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for ALT for subjects participating in Phase C of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[125] - 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.
[126] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	17	48	18
Units: Subjects				
ALT, Unknown, Day 21, Below [N=5,1,2,1]	0	0	0	0
ALT, Unknown, Day 21, Normal [N=5,1,2,1]	3	0	1	1
ALT, Unknown, Day 21, Above [N=5,1,2,1]	0	0	0	0
ALT, Unknown, Day 21, Unknown [N=5,1,2,1]	2	1	1	0
ALT, Normal, Day 21, Below [N=42,15,44,17]	0	0	0	0
ALT, Normal, Day 21, Normal [N=42,15,44,17]	41	12	40	17
ALT, Normal, Day 21, Above [N=42,15,44,17]	0	0	0	0
ALT, Normal, Day 21, Unknown [N=42,15,44,17]	1	3	4	0
ALT, Above, Day 21, Below [N=1,0,1,0]	0	0	0	0
ALT, Above, Day 21, Normal [N=1,0,1,0]	0	0	1	0
ALT, Above, Day 21, Above [N=1,0,1,0]	1	0	0	0
ALT, Above, Day 21, Unknown [N=1,0,1,0]	0	0	0	0
ALT, Unknown, Day 42, Below [N=5,2,2,1]	0	0	0	0
ALT, Unknown, Day 42, Normal [N=5,2,2,1]	5	2	2	1
ALT, Unknown, Day 42, Above [N=5,2,2,1]	0	0	0	0
ALT, Unknown, Day 42, Unknown [N=5,2,2,1]	0	0	0	0
ALT, Normal, Day 42, Below [N=42,15,45,17]	0	0	0	0
ALT, Normal, Day 42, Normal [N=42,15,45,17]	40	14	43	17
ALT, Normal, Day 42, Above [N=42,15,45,17]	0	0	0	0
ALT, Normal, Day 42, Unknown [N=42,15,45,17]	2	1	2	0
ALT, Above, Day 42, Below [N=1,0,1,0]	0	0	0	0

ALT, Above, Day 42, Normal [N=1,0,1,0]	1	0	1	0
ALT, Above, Day 42, Above [N=1,0,1,0]	0	0	0	0
ALT, Above, Day 42, Unknown [N=1,0,1,0]	0	0	0	0
ALT, Unknown, Month 6, Below [N=4,2,2,1]	0	0	0	0
ALT, Unknown, Month 6, Normal [N=4,2,2,1]	4	2	2	1
ALT, Unknown, Month 6, Above [N=4,2,2,1]	0	0	0	0
ALT, Unknown, Month 6, Unknown [N=4,2,2,1]	0	0	0	0
ALT, Normal , Month 6, Below [N=40,15,43,17]	0	0	0	0
ALT, Normal , Month 6, Normal [N=40,15,43,17]	36	13	41	17
ALT, Normal , Month 6, Above [N=40,15,43,17]	0	1	0	0
ALT, Normal , Month 6, Unknown [N=40,15,43,17]	4	1	2	0
ALT, Above, Month 6, Below [N=1,0,1,0]	0	0	0	0
ALT, Above, Month 6, Normal [N=1,0,1,0]	1	0	1	0
ALT, Above, Month 6, Above [N=1,0,1,0]	0	0	0	0
ALT, Above, Month 6, Unknown [N=1,0,1,0]	0	0	0	0
ALT, Unknown, Month 12, Below [N=3,2,3,1]	0	0	0	0
ALT, Unknown, Month 12, Normal [N=3,2,3,1]	3	2	2	1
ALT, Unknown, Month 12, Above [N=3,2,3,1]	0	0	1	0
ALT, Unknown, Month 12, Unknown [N=3,2,3,1]	0	0	0	0
ALT, Normal , Month 12, Below [N=40,15,44,17]	0	0	0	0
ALT, Normal , Month 12, Normal [N=40,15,44,17]	38	15	41	16
ALT, Normal , Month 12, Above [N=40,15,44,17]	0	0	1	0
ALT, Normal , Month 12, Unknown [N=40,15,44,17]	2	0	2	1
ALT, Above, Month 12, Below [N=1,0,1,0]	0	0	0	0
ALT, Above, Month 12, Normal [N=1,0,1,0]	1	0	1	0
ALT, Above, Month 12, Above [N=1,0,1,0]	0	0	0	0
ALT, Above, Month 12, Unknown [N=1,0,1,0]	0	0	0	0
ALT, Unknown, Month 24, Below [N=3,2,2,1]	0	0	0	0
ALT, Unknown, Month 24, Normal [N=3,2,2,1]	2	2	2	1
ALT, Unknown, Month 24, Above [N=3,2,2,1]	0	0	0	0
ALT, Unknown, Month 24, Unknown [N=3,2,2,1]	1	0	0	0

ALT, Normal , Month 24, Below [N=38,15,43,17]	0	0	0	0
ALT, Normal , Month 24, Normal [N=38,15,43,17]	36	15	41	17
ALT, Normal , Month 24, Above [N=38,15,43,17]	2	0	2	0
ALT, Normal , Month 24, Unknown [N=38,15,43,17]	0	0	0	0
ALT, Above, Month 24, Below [N=1,0,1,0]	0	0	0	0
ALT, Above, Month 24, Normal [N=1,0,1,0]	1	0	1	0
ALT, Above, Month 24, Above [N=1,0,1,0]	0	0	0	0
ALT, Above, Month 24, Unknown [N=1,0,1,0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST) in Study Phase C

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST) in Study Phase C[127][128]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for AST for subjects participating in Phase C of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[127] - 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.
[128] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	17	48	18
Units: Subjects				
AST, Unknown, Day 21, Below [N=5,1,2,1]	0	0	0	0

AST, Unknown, Day 21, Normal [N=5,1,2,1]	3	0	1	1
AST, Unknown, Day 21, Above [N=5,1,2,1]	0	0	0	0
AST, Unknown, Day 21, Unknown [N=5,1,2,1]	2	1	1	0
AST, Normal, Day 21, Below [N=40,12,44,17]	0	0	0	0
AST, Normal, Day 21, Normal [N=40,12,44,17]	39	10	40	17
AST, Normal, Day 21, Above [N=40,12,44,17]	0	0	0	0
AST, Normal, Day 21, Unknown [N=40,12,44,17]	1	2	4	0
AST, Above, Day 21, Below [N=3,3,1,0]	0	0	0	0
AST, Above, Day 21, Normal [N=3,3,1,0]	2	2	1	0
AST, Above, Day 21, Above[N=3,3,1,0]	1	0	0	0
AST, Above, Day 21, Unknown [N=3,3,1,0]	0	1	0	0
AST, Unknown, Day 42, Below [N=5,2,2,1]	0	0	0	0
AST, Unknown, Day 42, Normal [N=5,2,2,1]	5	2	1	1
AST, Unknown, Day 42, Above [N=5,2,2,1]	0	0	1	0
AST, Unknown, Day 42, Unknown [N=5,2,2,1]	0	0	0	0
AST, Normal, Day 42, Below [N=40,12,45,17]	0	0	0	0
AST, Normal, Day 42, Normal [N=40,12,45,17]	36	11	41	17
AST, Normal, Day 42, Above [N=40,12,45,17]	2	0	2	0
AST, Normal, Day 42, Unknown [N=40,12,45,17]	2	1	2	0
AST, Above, Day 42, Below [N=3,3,1,0]	0	0	0	0
AST, Above, Day 42, Normal [N=3,3,1,0]	3	1	1	0
AST, Above, Day 42, Above [N=3,3,1,0]	0	2	0	0
AST, Above, Day 42, Unknown [N=3,3,1,0]	0	0	0	0
AST, Unknown, Month 6, Below [N=4,2,2,1]	0	0	0	0
AST, Unknown, Month 6, Normal [N=4,2,2,1]	3	2	2	1
AST, Unknown, Month 6, Above [N=4,2,2,1]	0	0	0	0
AST, Unknown, Month 6, Unknown [N=4,2,2,1]	1	0	0	0
AST, Normal, Month 6, Below [N=39,12,43,17]	0	0	0	0
AST, Normal, Month 6, Normal [N=39,12,43,17]	34	9	40	17
AST, Normal, Month 6, Above [N=39,12,43,17]	1	2	1	0
AST, Normal, Month 6, Unknown [N=39,12,43,17]	4	1	2	0
AST, Above, Month 6, Below [N=2,3,1,0]	0	0	0	0

AST, Above, Month 6, Normal [N=2,3,1,0]	2	3	1	0
AST, Above, Month 6, Above [N=2,3,1,0]	0	0	0	0
AST, Above, Month 6, Unknown [N=2,3,1,0]	0	0	0	0
AST, Unknown, Month 12, Below [N=3,2,3,1]	0	0	0	0
AST, Unknown, Month 12, Normal [N=3,2,3,1]	3	2	2	1
AST, Unknown, Month 12, Above [N=3,2,3,1]	0	0	1	0
AST, Unknown, Month 12, Unknown [N=3,2,3,1]	0	0	0	0
AST, Normal, Month 12, Below [N=39,12,44,17]	0	0	0	0
AST, Normal, Month 12, Normal [N=39,12,44,17]	36	12	37	16
AST, Normal, Month 12, Above [N=39,12,44,17]	0	0	4	0
AST, Normal, Month 12, Unknown [N=39,12,44,17]	3	0	3	1
AST, Above, Month 12, Below [N=2,3,1,0]	0	0	0	0
AST, Above, Month 12, Normal [N=2,3,1,0]	2	3	1	0
AST, Above, Month 12, Above [N=2,3,1,0]	0	0	0	0
AST, Above, Month 12, Unknown [N=2,3,1,0]	0	0	0	0
AST, Unknown, Month 24, Below [N=3,2,2,1]	0	0	0	0
AST, Unknown, Month 24, Normal [N=3,2,2,1]	2	2	2	1
AST, Unknown, Month 24, Above [N=3,2,2,1]	0	0	0	0
AST, Unknown, Month 24, Unknown [N=3,2,2,1]	1	0	0	0
AST, Normal, Month 24, Below [N=37,12,43,17]	0	0	0	0
AST, Normal, Month 24, Normal [N=37,12,43,17]	34	12	42	17
AST, Normal, Month 24, Above [N=37,12,43,17]	3	0	1	0
AST, Normal, Month 24, Unknown [N=37,12,43,17]	0	0	0	0
AST, Above, Month 24, Below [N=2,3,1,0]	0	0	0	0
AST, Above, Month 24, Normal [N=2,3,1,0]	2	3	1	0
AST, Above, Month 24, Above [N=2,3,1,0]	0	0	0	0
AST, Above, Month 24, Unknown [N=2,3,1,0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA) in Study Phase C

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA) in Study Phase C[129][130]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for CREA for subjects participating in Phase C of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[129] - 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.
[130] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	17	48	18
Units: Subjects				
CREA,Unknown,Day 21,Below [N=5,1,2,1]	0	0	0	0
CREA,Unknown,Day 21,Normal [N=5,1,2,1]	3	0	1	1
CREA,Unknown,Day 21,Above [N=5,1,2,1]	0	0	0	0
CREA,Unknown,Day 21,Unknown [N=5,1,2,1]	2	1	1	0
CREA,Normal,Day 21,Below [N=43,15,45,17]	0	0	0	0
CREA,Normal,Day 21,Normal [N=43,15,45,17]	42	12	41	17
CREA,Normal,Day 21,Above [N=43,15,45,17]	0	0	0	0
CREA,Normal,Day 21,Unknown [N=43,15,45,17]	1	3	4	0
CREA,Unknown,Day 42,Below [N=5,2,2,1]	0	0	0	0
CREA,Unknown,Day 42,Normal [N=5,2,2,1]	5	2	2	1
CREA,Unknown,Day 42,Above [N=5,2,2,1]	0	0	0	0
CREA,Unknown,Day 42,Unknown [N=5,2,2,1]	0	0	0	0

CREA,Normal,Day 42,Below [N=43,15,46,17]	0	0	0	0
CREA,Normal,Day 42,Normal [N=43,15,46,17]	41	14	44	17
CREA,Normal,Day 42,Above [N=43,15,46,17]	0	0	0	0
CREA,Normal,Day 42,Unknown [N=43,15,46,17]	2	1	2	0
CREA,Unknown,Month 6,Below [N=4,2,2,1]	0	0	0	0
CREA,Unknown,Month 6,Normal [N=4,2,2,1]	4	2	2	1
CREA,Unknown,Month 6,Above [N=4,2,2,1]	0	0	0	0
CREA,Unknown,Month 6,Unknown [N=4,2,2,1]	0	0	0	0
CREA,Normal,Month 6,Below [N=41,15,44,17]	0	0	0	0
CREA,Normal,Month 6,Normal [N=41,15,44,17]	37	14	42	17
CREA,Normal,Month 6,Above [N=41,15,44,17]	0	0	0	0
CREA,Normal,Month 6,Unknown [N=41,15,44,17]	4	1	2	0
CREA,Unknown,Month 12,Below [N=3,2,3,1]	0	0	0	0
CREA,Unknown,Month 12,Normal [N=3,2,3,1]	3	2	3	1
CREA,Unknown,Month 12,Above [N=3,2,3,1]	0	0	0	0
CREA,Unknown,Month 12,Unknown [N=3,2,3,1]	0	0	0	0
CREA,Normal,Month 12,Below [N=41,15,45,17]	0	0	0	0
CREA,Normal,Month 12,Normal [N=41,15,45,17]	39	15	43	16
CREA,Normal,Month 12,Above [N=41,15,45,17]	0	0	0	0
CREA,Normal,Month 12,Unknown [N=41,15,45,17]	2	0	2	1
CREA,Unknown,Month 24,Below [N=3,2,2,1]	0	0	0	0
CREA,Unknown,Month 24,Normal [N=3,2,2,1]	2	2	2	1
CREA,Unknown,Month 24,Above [N=3,2,2,1]	0	0	0	0
CREA,Unknown,Month 24,Unknown [N=3,2,2,1]	1	0	0	0
CREA,Normal,Month 24,Below [N=39,15,44,17]	0	0	0	0
CREA,Normal,Month 24,Normal [N=39,15,44,17]	39	15	44	17
CREA,Normal,Month 24,Above [N=39,15,44,17]	0	0	0	0
CREA,Normal,Month 24,Unknown [N=39,15,44,17]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN) in Study Phase C

End point title	Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN) in Study Phase C[131][132]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for BUN for subjects participating in Phase C of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[131] - 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.
[132] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	17	48	18
Units: Subjects				
BUN,Unknown,Day 21,Below [N=5,1,1,1]	0	0	0	0
BUN,Unknown,Day 21,Normal [N=5,1,1,1]	3	0	0	1
BUN,Unknown,Day 21,Above [N=5,1,1,1]	0	0	0	0
BUN,Unknown,Day 21,Unknown [N=5,1,1,1]	2	1	1	0
BUN,Below,Day 21,Below [N=0,1,0,0]	0	0	0	0
BUN,Below,Day 21,Normal [N=0,1,0,0]	0	0	0	0
BUN,Below,Day 21,Above [N=0,1,0,0]	0	0	0	0
BUN,Below,Day 21,Unknown [N=0,1,0,0]	0	1	0	0
BUN,Normal,Day 21,Below [N=41,11,45,17]	1	0	0	0
BUN,Normal,Day 21,Normal [N=41,11,45,17]	37	9	41	16
BUN,Normal,Day 21,Above [N=41,11,45,17]	2	0	0	1
BUN,Normal,Day 21,Unknown [N=41,11,45,17]	1	2	4	0
BUN,Above,Day 21,Below [N=2,3,1,0]	0	0	0	0
BUN,Above,Day 21,Normal [N=2,3,1,0]	2	3	1	0

BUN,Above,Day 21,Above [N=2,3,1,0]	0	0	0	0
BUN,Above,Day 21,Unknown [N=2,3,1,0]	0	0	0	0
BUN,Unknown,Day 42,Below [N=5,2,1,1]	0	0	0	0
BUN,Unknown,Day 42,Normal [N=5,2,1,1]	5	2	1	1
BUN,Unknown,Day 42,Above [N=5,2,1,1]	0	0	0	0
BUN,Unknown,Day 42,Unknown [N=5,2,1,1]	0	0	0	0
BUN,Below,Day 42,Below [N=0,1,0,0]	0	0	0	0
BUN,Below,Day 42,Normal [N=0,1,0,0]	0	1	0	0
BUN,Below,Day 42,Above [N=0,1,0,0]	0	0	0	0
BUN,Below,Day 42,Unknown [N=0,1,0,0]	0	0	0	0
BUN,Normal,Day 42,Below [N=41,11,46,17]	0	0	3	0
BUN,Normal,Day 42,Normal [N=41,11,46,17]	37	11	38	16
BUN,Normal,Day 42,Above [N=41,11,46,17]	2	0	3	1
BUN,Normal,Day 42,Unknown [N=41,11,46,17]	2	0	2	0
BUN,Above,Day 42,Below [N=2,3,1,0]	0	0	0	0
BUN,Above,Day 42,Normal [N=2,3,1,0]	1	2	1	0
BUN,Above,Day 42,Above [N=2,3,1,0]	1	0	0	0
BUN,Above,Day 42,Unknown [N=2,3,1,0]	0	1	0	0
BUN,Unknown,Month 6,Below [N=4,2,1,1]	0	0	0	0
BUN,Unknown,Month 6,Normal [N=4,2,1,1]	4	2	1	1
BUN,Unknown,Month 6,Above [N=4,2,1,1]	0	0	0	0
BUN,Unknown,Month 6,Unknown [N=4,2,1,1]	0	0	0	0
BUN,Below,Month 6,Below [N=0,1,0,0]	0	0	0	0
BUN,Below,Month 6,Normal [N=0,1,0,0]	0	1	0	0
BUN,Below,Month 6,Above [N=0,1,0,0]	0	0	0	0
BUN,Below,Month 6,Unknown [N=0,1,0,0]	0	0	0	0
BUN,Normal,Month 6,Below [N=39,11,44,17]	0	0	2	0
BUN,Normal,Month 6,Normal [N=39,11,44,17]	34	10	35	17
BUN,Normal,Month 6,Above [N=39,11,44,17]	1	0	5	0
BUN,Normal,Month 6,Unknown [N=39,11,44,17]	4	1	2	0
BUN,Above,Month 6,Below [N=2,3,1,0]	0	0	0	0
BUN,Above,Month 6,Normal [N=2,3,1,0]	2	2	0	0
BUN,Above,Month 6,Above [N=2,3,1,0]	0	1	1	0
BUN,Above,Month 6,Unknown [N=2,3,1,0]	0	0	0	0
BUN,Unknown,Month 12,Below [N=3,2,2,1]	0	0	0	0
BUN,Unknown,Month 12,Normal [N=3,2,2,1]	3	2	1	1

BUN,Unknown,Month 12,Above [N=3,2,2,1]	0	0	1	0
BUN,Unknown,Month 12,Unknown [N=3,2,2,1]	0	0	0	0
BUN,Below,Month 12,Below [N=0,1,0,0]	0	0	0	0
BUN,Below,Month 12,Normal [N=0,1,0,0]	0	1	0	0
BUN,Below,Month 12,Above [N=0,1,0,0]	0	0	0	0
BUN,Below,Month 12,Unknown [N=0,1,0,0]	0	0	0	0
BUN,Normal,Month12,Below [N=39,11,45,17]	0	0	0	0
BUN,Normal,Month12,Normal [N=39,11,45,17]	36	10	41	16
BUN,Normal,Month12,Above [N=39,11,45,17]	1	1	2	0
BUN,Normal,Month12,Unknown [N=39,11,45,17]	2	0	2	1
BUN,Above,Month 12,Below [N=2,3,1,0]	0	0	0	0
BUN,Above,Month 12,Normal [N=2,3,1,0]	2	2	1	0
BUN,Above,Month 12,Above [N=2,3,1,0]	0	1	0	0
BUN,Above,Month 12,Unknown [N=2,3,1,0]	0	0	0	0
BUN,Unknown,Month 24,Below [N=3,2,1,1]	0	0	0	0
BUN,Unknown,Month 24,Normal [N=3,2,1,1]	2	2	1	1
BUN,Unknown,Month 24,Above [N=3,2,1,1]	0	0	0	0
BUN,Unknown,Month 24,Unknown [N=3,2,1,1]	1	0	0	0
BUN,Below,Month 24,Below [N=0,1,0,0]	0	0	0	0
BUN,Below,Month 24,Normal [N=0,1,0,0]	0	1	0	0
BUN,Below,Month 24,Above [N=0,1,0,0]	0	0	0	0
BUN,Below,Month 24,Unknown [N=0,1,0,0]	0	0	0	0
BUN,Normal,Month 24,Below [N=37,11,44,17]	0	0	1	0
BUN,Normal,Month 24,Normal [N=37,11,44,17]	35	9	39	16
BUN,Normal,Month 24,Above [N=37,11,44,17]	2	2	4	1
BUN,Normal,Month 24,Unknown [N=37,11,44,17]	0	0	0	0
BUN,Above,Month 24,Below [N=2,3,1,0]	0	0	0	0
BUN,Above,Month 24,Normal [N=2,3,1,0]	2	3	0	0
BUN,Above,Month 24,Above [N=2,3,1,0]	0	0	1	0
BUN,Above,Month 24,Unknown [N=2,3,1,0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status With Regards to Creatine Phosphokinase (CPK) in Study Phase C

End point title	Number of Subjects With Changed Status With Regards to Creatine Phosphokinase (CPK) in Study Phase C[133][134]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for CPK for subjects participating in Phase C of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[133] - 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.
[134] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to Creatine Phosphokinase (CPK)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	17	48	18
Units: Subjects				
CPK,Unknown,Day 21,Below [N=5,1,2,1]	0	0	0	0
CPK,Unknown,Day 21,Normal [N=5,1,2,1]	3	0	0	1
CPK,Unknown,Day 21,Above [N=5,1,2,1]	0	0	1	0
CPK,Unknown,Day 21,Unknown [N=5,1,2,1]	2	1	1	0
CPK,Normal,Day 21,Below [N=42,13,41,16]	0	0	0	0
CPK,Normal,Day 21,Normal [N=42,13,41,16]	39	19	37	14
CPK,Normal,Day 21,Above [N=42,13,41,16]	2	0	0	2
CPK,Normal,Day 21,Unknown [N=42,13,41,16]	1	3	4	0
CPK,Above,Day 21,Below [N=1,2,4,1]	0	0	0	0
CPK,Above,Day 21,Normal [N=1,2,4,1]	1	1	4	1
CPK,Above,Day 21,Above [N=1,2,4,1]	0	1	0	0
CPK,Above,Day 21,Unknown [N=1,2,4,1]	0	0	0	0
CPK,Unknown,Day 42,Below [N=5,2,2,1]	0	0	0	0
CPK,Unknown,Day 42,Normal [N=5,2,2,1]	5	1	2	1

CPK,Unknown,Day 42,Above [N=5,2,2,1]	0	1	0	0
CPK,Unknown,Day 42,Unknown [N=5,2,2,1]	0	0	0	0
CPK,Normal,Day 42,Below [N=42,13,42,16]	0	0	0	0
CPK,Normal,Day 42,Normal [N=42,13,42,16]	39	11	40	15
CPK,Normal,Day 42,Above [N=42,13,42,16]	1	1	0	1
CPK,Normal,Day 42,Unknown [N=42,13,42,16]	2	1	2	0
CPK,Above,Day 42,Below [N=1,2,4,1]	0	0	0	0
CPK,Above,Day 42,Normal [N=1,2,4,1]	0	1	4	1
CPK,Above,Day 42,Above [N=1,2,4,1]	1	1	0	0
CPK,Above,Day 42,Unknown [N=1,2,4,1]	0	0	0	0
CPK,Unknown,Month 6,Below [N=4,2,2,1]	0	0	0	0
CPK,Unknown,Month 6,Normal [N=4,2,2,1]	3	2	2	1
CPK,Unknown,Month 6,Above [N=4,2,2,1]	1	0	0	0
CPK,Unknown,Month 6,Unknown [N=4,2,2,1]	0	0	0	0
CPK,Normal,Month 6,Below [N=40,13,40,16]	0	0	0	0
CPK,Normal,Month 6,Normal [N=40,13,40,16]	34	12	36	16
CPK,Normal,Month 6,Above [N=40,13,40,16]	2	0	3	0
CPK,Normal,Month 6,Unknown [N=40,13,40,16]	4	1	1	0
CPK,Above,Month 6,Below [N=1,2,4,1]	0	0	0	0
CPK,Above,Month 6,Normal [N=1,2,4,1]	0	1	3	1
CPK,Above,Month 6,Above [N=1,2,4,1]	1	1	0	0
CPK,Above,Month 6,Unknown [N=1,2,4,1]	0	0	1	0
CPK,Unknown,Month 12,Below [N=3,2,3,1]	0	0	0	0
CPK,Unknown,Month 12,Normal [N=3,2,3,1]	2	2	2	1
CPK,Unknown,Month 12,Above [N=3,2,3,1]	1	0	1	0
CPK,Unknown,Month 12,Unknown [N=3,2,3,1]	0	0	0	0
CPK,Normal,Month 12,Below [N=40,13,41,16]	0	0	0	0
CPK,Normal,Month 12,Normal [N=40,13,41,16]	35	12	36	14
CPK,Normal,Month 12,Above [N=40,13,41,16]	3	1	3	1
CPK,Normal,Month 12,Unknown [N=40,13,41,16]	2	0	2	1
CPK,Above,Month 12,Below [N=1,2,4,1]	0	0	0	0
CPK,Above,Month 12,Normal [N=1,2,4,1]	1	1	4	1
CPK,Above,Month 12,Above [N=1,2,4,1]	0	1	0	0
CPK,Above,Month 12,Unknown [N=1,2,4,1]	0	0	0	0

CPK,Unknown,Month 24,Below [N=3,2,2,1]	0	0	0	0
CPK,Unknown,Month 24,Normal [N=3,2,2,1]	2	2	2	1
CPK,Unknown,Month 24,Above [N=3,2,2,1]	0	0	0	0
CPK,Unknown,Month 24,Unknown [N=3,2,2,1]	1	0	0	0
CPK,Normal,Month 24,Below [N=38,13,40,16]	0	0	0	0
CPK,Normal,Month 24,Normal [N=38,13,40,16]	36	12	38	14
CPK,Normal,Month 24,Above [N=38,13,40,16]	2	1	2	2
CPK,Normal,Month 24,Unknown [N=38,13,40,16]	0	0	0	0
CPK,Above,Month 24,Below [N=1,2,4,1]	0	0	0	0
CPK,Above,Month 24,Normal [N=1,2,4,1]	1	1	3	1
CPK,Above,Month 24,Above [N=1,2,4,1]	0	1	1	0
CPK,Above,Month 24,Unknown [N=1,2,4,1]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Changed Status With Regards to Lactate Dehydrogenase (LDH) in Study Phase C

End point title	Number of Subjects With Changed Status With Regards to Lactate Dehydrogenase (LDH) in Study Phase C[135][136]

End point description:

Changes from baseline are categorised as below, within, or above the normal ranges at each scheduled post-vaccination time point versus the category of the laboratory values at baseline. Assessed parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK) Per parameter and range, it was assessed according to baseline values whether laboratory values of the subjects were below normal, normal or above the normal range. This outcome presents results for LDH for subjects participating in Phase C of the study.

End point type	Primary

End point timeframe:

At Days 21, and 42, and at Months 6, 12 and 24

Notes:

[135] - 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.
[136] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to Lactate Dehydrogenase (LDH)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	17	48	18
Units: Subjects				
LDH,Unknown,Day 21,Below [N=5,1,1,1]	0	0	0	0
LDH,Unknown,Day 21,Normal [N=5,1,1,1]	2	0	0	1
LDH,Unknown,Day 21,Above [N=5,1,1,1]	1	0	0	0
LDH,Unknown,Day 21,Unknown [N=5,1,1,1]	2	1	1	0
LDH,Normal,Day 21,Below [N=35,12,43,17]	0	0	0	0
LDH,Normal,Day 21,Normal [N=35,12,43,17]	31	9	37	16
LDH,Normal,Day 21,Above [N=35,12,43,17]	4	1	2	1
LDH,Normal,Day 21,Unknown [N=35,12,43,17]	0	2	4	0
LDH,Above,Day 21,Below [N=8,3,3,0]	0	0	0	0
LDH,Above,Day 21,Normal [N=8,3,3,0]	5	2	2	0
LDH,Above,Day 21,Above [N=8,3,3,0]	2	0	1	0
LDH,Above,Day 21,Unknown [N=8,3,3,0]	1	1	0	0
LDH,Unknown,Day 42,Below [N=5,2,1,1]	0	0	0	0
LDH,Unknown,Day 42,Normal [N=5,2,1,1]	4	0	1	1
LDH,Unknown,Day 42,Above [N=5,2,1,1]	1	2	0	0
LDH,Unknown,Day 42,Unknown [N=5,2,1,1]	0	0	0	0
LDH,Normal,Day 42,Below [N=35,12,44,17]	0	0	0	0
LDH,Normal,Day 42,Normal [N=35,12,44,17]	29	7	39	16
LDH,Normal,Day 42,Above [N=35,12,44,17]	4	4	3	1
LDH,Normal,Day 42,Unknown [N=35,12,44,17]	2	1	2	0
LDH,Above,Day 42,Below [N=8,3,3,0]	0	0	0	0
LDH,Above,Day 42,Normal [N=8,3,3,0]	2	1	2	0
LDH,Above,Day 42,Above [N=8,3,3,0]	6	2	1	0
LDH,Above,Day 42,Unknown [N=8,3,3,0]	0	0	0	0
LDH, Unknown, Month 6, Below [N=4,2,1,1]	0	0	0	0
LDH, Unknown, Month 6, Normal [N=4,2,1,1]	2	0	1	1
LDH,Unknown, Month 6, Above [N=4,2,1,1]	1	2	0	0
LDH, Unknown, Month 6, Unknown [N=4,2,1,1]	1	0	0	0
LDH, Normal, Month 6, Below [N=34,12,42,17]	0	0	0	0
LDH, Normal, Month 6, Normal [N=34,12,42,17]	28	8	37	17

LDH, Normal, Month 6, Above [N=34,12,42,17]	2	3	3	0
LDH, Normal, Month 6, Unknown [N=34,12,42,17]	4	1	2	0
LDH, Above, Month 6, Below [N=7,3,3,0]	0	0	0	0
LDH, Above, Month 6, Normal [N=7,3,3,0]	2	2	2	0
LDH, Above, Month 6, Above [N=7,3,3,0]	5	1	1	0
LDH, Above, Month 6, Unknown [N=7,3,3,0]	0	0	0	0
LDH, Unknown, Month 12, Below [N=3,2,2,1]	0	0	0	0
LDH, Unknown, Month 12, Normal [N=3,2,2,1]	3	2	0	1
LDH, Unknown, Month 12, Above [N=3,2,2,1]	0	0	2	0
LDH, Unknown, Month 12, Unknown [N=3,2,2,1]	0	0	0	0
LDH, Normal, Month 12, Below [N=34,12,43,17]	0	0	0	0
LDH, Normal, Month 12, Normal [N=34,12,43,17]	26	9	34	14
LDH, Normal, Month 12, Above [N=34,12,43,17]	6	3	6	2
LDH, Normal, Month 12, Unknwon [N=34,12,43,17]	2	0	3	1
LDH, Above, Month 12, Below [N=7,3,3,0]	0	0	0	0
LDH, Above, Month 12, Normal [N=7,3,3,0]	1	1	2	0
LDH, Above, Month 12, Above [N=7,3,3,0]	5	2	1	0
LDH, Above, Month 12, Unknown [N=7,3,3,0]	1	0	0	0
LDH, Unknown, Month 24, Below [N=3,2,1,1]	0	0	0	0
LDH, Unknown, Month 24, Normal [N=3,2,1,1]	2	2	1	1
LDH, Unknown, Month 24, Above [N=3,2,1,1]	0	0	0	0
LDH, Unknown, Month 24, Unknown [N=3,2,1,1]	1	0	0	0
LDH, Normal, Month 24, Below [N=32,12,42,17]	0	0	0	0
LDH, Normal, Month 24, Normal [N=32,12,42,17]	24	10	40	16
LDH, Normal, Month 24, Above [N=32,12,42,17]	8	2	2	1
LDH, Normal, Month 24, Unknown [N=32,12,42,17]	0	0	0	0
LDH, Above, Month 24, Below [N=7,3,3,0]	0	0	0	0
LDH, Above, Month 24, Normal [N=7,3,3,0]	2	2	2	0
LDH, Above, Month 24, Above [N=7,3,3,0]	5	1	1	0
LDH, Above, Month 24, Unknown [N=7,3,3,0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Alanine Aminotransferase (ALT) in Study Phase A

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Alanine Aminotransferase (ALT) in Study Phase A[137][138]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents ALT results for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[137] - 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.
[138] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Alanine Aminotransferase (ALT)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	18
Units: Subjects				
ALT, Day 0, Below [N=52,18,53,17]	0	0	0	0
ALT, Day 0, Normal [N=52,18,53,17]	50	18	51	17
ALT, Day 0, Above [N=52,18,53,17]	2	0	2	0
ALT, Day 21, Below [N=48,16,44,18]	0	0	0	0
ALT, Day 21, Normal [N=48,16,44,18]	48	16	44	18
ALT, Day 21, Above [N=48,16,44,18]	0	0	0	0
ALT, Day 42, Below [N=49,16,45,16]	0	0	0	0
ALT, Day 42, Normal [N=49,16,45,16]	49	15	45	16
ALT, Day 42, Above [N=49,16,45,16]	0	1	0	0
ALT, Month 6, Below [N=49,15,43,17]	0	0	0	0
ALT, Month 6, Normal [N=49,15,43,17]	48	15	42	17
ALT, Month 6, Above [N=49,15,43,17]	1	0	1	0
ALT, Month 12, Below [N=47,17,42,17]	0	0	0	0

ALT, Month 12, Normal [N=47,17,42,17]	46	17	41	17
ALT, Month 12, Above [N=47,17,42,17]	1	0	1	0
ALT, Month 24, Below [N=47,16,40,14]	0	0	0	0
ALT, Month 24, Normal [N=47,16,40,14]	47	16	40	14
ALT, Month 24, Above [N=47,16,40,14]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Aspartate Aminotransferase (AST) in Study Phase A

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Aspartate Aminotransferase (AST) in Study Phase A[139][140]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents AST results for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[139] - 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.
[140] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Aspartate Aminotransferase (AST)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	49	17
Units: Subjects				
AST, Day 0, Below [N=52,18,53,17]	0	0	0	0
AST, Day 0, Normal [N=52,18,53,17]	46	18	51	17
AST, Day 0, Above [N=52,18,53,17]	6	0	2	0
AST, Day 21, Below [N=48,16,44,17]	0	0	0	0
AST, Day 21, Normal [N=48,16,44,17]	42	16	44	17
AST, Day 21, Above [N=48,16,44,17]	6	0	0	0
AST, Day 42, Below [N=49,15,45,16]	0	0	0	0
AST, Day 42, Normal [N=49,15,45,16]	46	13	45	16
AST, Day 42, Above [N=49,15,45,16]	3	2	0	0
AST, Month 6, Below [N=49,15,43,17]	0	0	0	0
AST, Month 6, Normal [N=49,15,43,17]	46	14	42	17

AST, Month 6, Above [N=49,15,43,17]	3	1	1	0
AST, Month 12, Below [N=49,15,43,17]	0	0	0	0
AST, Month 12, Normal [N=49,15,43,17]	43	16	42	17
AST, Month 12, Above [N=49,15,43,17]	4	1	0	0
AST, Month 24, Below [N=47,16,40,14]	0	0	0	0
AST, Month 24, Normal [N=47,16,40,14]	44	16	40	14
AST, Month 24, Above [N=47,16,40,14]	3	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Blood Urea Nitrogen (BUN) in Study Phase A

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Blood Urea Nitrogen (BUN) in Study Phase A[141][142]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents BUN results for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[141] - 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.
[142] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Blood Urea Nitrogen (BUN)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	18
Units: Subjects				
BUN, Day 0, Below [N=52,18,53,17]	0	0	0	0
BUN, Day 0, Normal [N=52,18,53,17]	50	18	52	16
BUN, Day 0, Above [N=52,18,53,17]	2	0	1	1
BUN, Day 21, Below [N=48,16,44,18]	0	1	0	0
BUN, Day 21, Normal [N=48,16,44,18]	45	14	39	16
BUN, Day 21, Above [N=48,16,44,18]	3	1	5	2
BUN, Day 42, Below [N=49,16,45,16]	0	0	0	0
BUN, Day 42, Normal [N=49,16,45,16]	42	16	39	14
BUN, Day 42, Above [N=49,16,45,16]	7	0	6	2

BUN, Month 6, Below [N=49,15,43,17]	0	1	0	0
BUN, Month 6, Normal [N=49,15,43,17]	46	13	39	15
BUN, Month 6, Above [N=49,15,43,17]	3	1	4	2
BUN, Month 12, Below [N=47,17,42,17]	0	0	1	0
BUN, Month 12, Normal [N=47,17,42,17]	42	16	41	15
BUN, Month 12, Above [N=47,17,42,17]	5	1	0	2
BUN, Month 24, Below [N=47,16,40,14]	0	0	1	0
BUN, Month 24, Normal [N=47,16,40,14]	45	16	38	12
BUN, Month 24, Above [N=47,16,40,14]	2	0	1	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatinine (CREA) in Study Phase A

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatinine (CREA) in Study Phase A[143][144]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents CREA results, for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[143] - 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.
[144] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatinine (CREA)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	18
Units: Subjects				
CREA, Day 0, Below [N=52,18,53,17]	0	0	0	0
CREA, Day 0, Normal [N=52,18,53,17]	52	18	53	17
CREA, Day 0, Above [N=52,18,53,17]	0	0	0	0
CREA, Day 21, Below [N=48,16,44,18]	0	0	0	0
CREA, Day 21, Normal [N=48,16,44,18]	48	16	42	18
CREA, Day 21, Above [N=48,16,44,18]	0	0	2	0
CREA, Day 42, Below [N=49,16,45,16]	0	0	0	0

CREA, Day 42, Normal [N=49,16,45,16]	49	16	43	16
CREA, Day 42, Above [N=49,16,45,16]	0	0	2	0
CREA, Month 6, Below [N=49,15,43,17]	0	0	0	0
CREA, Month 6, Normal [N=49,15,43,17]	49	15	43	17
CREA, Month 6, Above [N=49,15,43,17]	0	0	0	0
CREA, Month 12, Below [N=47,17,42,17]	0	0	0	0
CREA, Month 12, Normal [N=47,17,42,17]	47	17	42	17
CREA, Month 12, Above [N=47,17,42,17]	0	0	0	0
CREA, Month 24, Below [N=47,16,40,14]	0	0	0	0
CREA, Month 24, Normal [N=47,16,40,14]	47	16	39	14
CREA, Month 24, Above [N=47,16,40,14]	0	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatine Phosphokinase (CPK) in Study Phase A

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatine Phosphokinase (CPK) in Study Phase A[145][146]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents CPK results for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[145] - 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.
[146] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatine Phosphokinase (CPK)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	18
Units: Subjects				
CPK, Day 0, Below [N=52,18,53,17]	0	0	0	0

CPK, Day 0, Normal [N=52,18,53,17]	51	17	51	17
CPK, Day 0, Above [N=52,18,53,17]	1	1	2	0
CPK, Day 21, Below [N=48,16,44,18]	0	0	0	0
CPK, Day 21, Normal [N=48,16,44,18]	46	16	42	17
CPK, Day 21, Above [N=48,16,44,18]	2	0	2	1
CPK, Day 42, Below [N=49,16,45,16]	0	0	0	0
CPK, Day 42, Normal [N=49,16,45,16]	47	14	42	15
CPK, Day 42, Above [N=49,16,45,16]	2	2	3	1
CPK, Month 6, Below [N=49,15,43,17]	0	0	0	0
CPK, Month 6, Normal [N=49,15,43,17]	47	14	38	16
CPK, Month 6, Above [N=49,15,43,17]	2	1	5	1
CPK, Month 12, Below [N=47,17,42,17]	0	0	0	0
CPK, Month 12, Normal [N=47,17,42,17]	45	15	40	16
CPK, Month 12, Above [N=47,17,42,17]	2	2	2	1
CPK, Month 24, Below [N=47,16,39,14]	0	0	0	0
CPK, Month 24, Normal [N=47,16,39,14]	47	15	36	13
CPK, Month 24, Above [N=47,16,39,14]	0	1	3	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Lactate Dehydrogenase (LDH) in Study Phase A

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Lactate Dehydrogenase (LDH) in Study Phase A[147][148]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents LDH results for subjects participating in Phase A of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[147] - 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.
[148] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Lactate Dehydrogenase (LDH)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	17
Units: Subjects				
LDH, Day 0, Below [N=52,18,53,17]	0	0	0	0
LDH, Day 0, Normal [N=52,18,53,17]	41	12	52	17
LDH, Day 0, Above [N=52,18,53,17]	11	6	1	0
LDH, Day 21, Below [N=48,16,44,17]	0	0	0	0
LDH, Day 21, Normal [N=48,16,44,17]	42	10	41	15
LDH, Day 21, Above [N=48,16,44,17]	6	6	3	2
LDH, Day 42, Below [N=49,15,45,16]	0	0	0	0
LDH, Day 42, Normal [N=49,15,45,16]	38	9	42	15
LDH, Day 42, Above [N=49,15,45,16]	11	6	4	1
LDH, Month 6, Below [N=49,15,43,17]	0	0	0	0
LDH, Month 6, Normal [N=49,15,43,17]	37	11	39	14
LDH, Month 6, Above [N=49,15,43,17]	12	4	4	3
LDH, Month 12, Below [N=47,17,42,17]	0	0	0	0
LDH, Month 12, Normal [N=47,17,42,17]	40	12	41	15
LDH, Month 12, Above [N=47,17,42,17]	7	5	1	2
LDH, Month 24, Below [N=47,16,39,14]	0	0	0	0
LDH, Month 24, Normal [N=47,16,39,14]	42	13	36	12
LDH, Month 24, Above [N=47,16,39,14]	5	3	3	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Alanine Aminotransferase (ALT) in Study Phase B

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Alanine Aminotransferase (ALT) in Study Phase B[149][150]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents AST results, for subjects participating to Phase B of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[149] - 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.
[150] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed

Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	48	17
Units: Subjects				
ALT, Day 0, Below [N=51,16,48,17]	0	0	0	0
ALT, Day 0, Normal [N=51,16,48,17]	50	16	48	16
ALT, Day 0, Above [N=51,16,48,17]	1	0	0	1
ALT, Day 21, Below [N=45,17,46,17]	0	0	0	0
ALT, Day 21, Normal [N=45,17,46,17]	44	16	45	17
ALT, Day 21, Above [N=45,17,46,17]	1	1	1	0
ALT, Day 42, Below [N=47,17,47,17]	0	0	0	0
ALT, Day 42, Normal [N=47,17,47,17]	46	17	45	16
ALT, Day 42, Above [N=47,17,47,17]	1	0	2	1
ALT, Month 6, Below [N=41,16,43,17]	0	0	0	0
ALT, Month 6, Normal [N=41,16,43,17]	41	16	43	17
ALT, Month 6, Above [N=41,16,43,17]	0	0	0	0
ALT, Month 12, Below [N=44,17,45,17]	0	0	0	0
ALT, Month 12, Normal [N=44,17,45,17]	44	17	45	17
ALT, Month 12, Above [N=44,17,45,17]	0	0	0	0
ALT, Month 24, Below [N=45,17,44,17]	0	0	0	0
ALT, Month 24, Normal [N=45,17,44,17]	44	17	43	17
ALT, Month 24, Above [N=45,17,44,17]	1	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Aspartate Aminotransferase (AST) in Study Phase B

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Aspartate Aminotransferase (AST) in Study Phase B[151][152]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents AST results, for subjects participating to Phase B of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[151] - 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.

[152] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	16	48	17
Units: Subjects				
AST, Day 0, Below [N=51,16,48,17]	0	0	0	0
AST, Day 0, Normal [N=51,16,48,17]	48	15	45	16
AST, Day 0, Above [N=51,16,48,17]	3	1	3	1
AST, Day 21, Below [N=44,17,46,17]	0	0	0	0
AST, Day 21, Normal [N=44,17,46,17]	41	16	45	17
AST, Day 21, Above [N=44,17,46,17]	3	1	1	0
AST, Day 42, Below [N=47,17,47,17]	0	0	0	0
AST, Day 42, Normal [N=47,17,47,17]	42	15	44	16
AST, Day 42, Above [N=47,17,47,17]	5	2	3	1
AST, Month 6, Below [N=42,16,42,17]	0	0	0	0
AST, Month 6, Normal [N=42,16,42,17]	40	15	42	17
AST, Month 6, Above [N=42,16,42,17]	2	1	0	0
AST, Month 12, Below [N=44,17,45,17]	0	0	0	0
AST, Month 12, Normal [N=44,17,45,17]	44	17	45	17
AST, Month 12, Above [N=44,17,45,17]	0	0	0	0
AST, Month 24, Below [N=45,17,44,17]	0	0	0	0
AST, Month 24, Normal [N=45,17,44,17]	44	17	43	17
AST, Month 24, Above [N=45,17,44,17]	1	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatinine (CREA) in Study Phase B

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatinine (CREA) in Study Phase B[153][154]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents CREA results, for subjects participating in Phase B of the study.

End point type	Primary

End point timeframe:

At Days 0, 21 and 42 and at Month 6, 12 and 24

Notes:

[153] - 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.

[154] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Creatinine (CREA)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	48	17
Units: Subjects				
CREA, Day 0, Below [N=51,16,48,17]	0	0	0	0
CREA, Day 0, Normal [N=51,16,48,17]	51	16	47	17
CREA, Day 0, Above [N=51,16,48,17]	0	0	1	0
CREA, Day 21, Below [N=45,17,46,17]	0	0	0	0
CREA, Day 21, Normal [N=45,17,46,17]	44	17	45	17
CREA, Day 21, Above [N=45,17,46,17]	1	0	1	0
CREA, Day 42, Below [N=47,17,47,17]	0	0	0	0
CREA, Day 42, Normal [N=47,17,47,17]	46	17	47	17
CREA, Day 42, Above [N=47,17,47,17]	1	0	0	0
CREA, Month 6, Below [N=42,16,43,17]	0	0	0	0
CREA, Month 6, Normal [N=42,16,43,17]	42	16	41	17
CREA, Month 6, Above [N=42,16,43,17]	0	0	2	0
CREA, Month 12, Below [N=44,17,45,17]	0	0	0	0
CREA, Month 12, Normal [N=44,17,45,17]	44	17	44	17
CREA, Month 12, Above [N=44,17,45,17]	0	0	1	0
CREA, Month 24, Below [N=44,17,45,17]	0	0	0	0
CREA, Month 24, Normal [N=44,17,45,17]	45	17	44	17
CREA, Month 24, Above [N=44,17,45,17]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Lactate Dehydrogenase (LDH) in Study Phase B

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Lactate Dehydrogenase (LDH) in Study Phase B[155][156]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase

(AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents LDH results, for subjects participating to Phase B of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[155] - 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.
[156] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to Lactate Dehydrogenase (LDH)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	48	17
Units: Subjects				
LDH, Day 0, Below [N=51,16,48,17]	0	0	0	0
LDH, Day 0, Normal [N=51,16,48,17]	46	14	41	15
LDH, Day 0, Above [N=51,16,48,17]	5	2	7	2
LDH, Day 21, Below [N=44,17,46,17]	0	0	0	0
LDH, Day 21, Normal [N=44,17,46,17]	35	14	42	16
LDH, Day 21, Above [N=44,17,46,17]	9	3	4	1
LDH, Day 42, Below [N=47,17,47,17]	0	0	0	0
LDH, Day 42, Normal [N=47,17,47,17]	35	10	41	14
LDH, Day 42, Above [N=47,17,47,17]	12	7	6	3
LDH, Month 6, Below [N=41,16,42,17]	0	0	0	0
LDH, Month 6, Normal [N=41,16,42,17	35	11	36	15
LDH, Month 6, Above [N=41,16,42,17]	6	5	6	2
LDH, Month 12, Below [N=44,17,45,17]	0	0	0	0
LDH, Month 12, Normal [N=44,17,45,17]	35	12	42	16
LDH, Month 12, Above [N=44,17,45,17]	9	5	3	1
LDH, Month 24, Below [N=45,17,44,17]	0	0	0	0
LDH, Month 24, Normal [N=45,17,44,17]	43	16	41	15
LDH, Month 24, Above [N=45,17,44,17]	2	1	3	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Blood Urea Nitrogen (BUN) in Study Phase C

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Blood Urea Nitrogen

	(BUN) in Study Phase C[157][158]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents BUN results, for subjects participating to Phase C of the study.

End point type	Primary

End point timeframe:

At Days 0, 21 and 42 and at Months 6, 12 and 24

Notes:

[157] - 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.
[158] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	17	47	18
Units: Subjects				
BUN, Day 0, Below [N=44,15,47,17]	0	1	0	0
BUN, Day 0, Normal [N=44,15,47,17]	42	11	46	17
BUN, Day 0, Above [N=44,15,47,17]	2	3	1	0
BUN, Day 21, Below [N=45,12,42,18]	1	0	0	0
BUN, Day 21, Normal [N=45,12,42,18]	42	12	42	17
BUN, Day 21, Above [N=45,12,42,18]	2	0	0	1
BUN, Day 42, Below [N=46,16,46,18]	0	0	3	0
BUN, Day 42, Normal [N=46,16,46,18]	43	16	40	17
BUN, Day 42, Above [N=46,16,46,18]	3	0	3	1
BUN, Month 6, Below[N=41,16,44,18]	0	0	2	0
BUN, Month 6, Normal [N=41,16,44,18]	40	15	36	18
BUN, Month 6, Above [N=41,16,44,18]	1	1	6	0
BUN, Month 12, Below [N=42,12,46,17]	0	0	0	0
BUN, Month 12, Normal [N=42,12,46,17]	41	15	43	17
BUN, Month 12, Above [N=42,12,46,17]	1	2	3	0
BUN, Month 24, Below [N=41,17,46,18]	0	0	1	0
BUN, Month 24, Normal [N=41,17,46,18]	39	15	40	17
BUN, Month 24, Above [N=41,17,46,18]	2	2	5	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Blood Urea Nitrogen (BUN) in Study Phase B

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Blood Urea Nitrogen (BUN) in Study Phase B[159][160]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents BUN results, for subjects participating to Phase B of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[159] - 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.
[160] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Blood Urea Nitrogen (BUN)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	48	17
Units: Subjects				
BUN, Day 0, Below [N=51,16,48,16]	0	0	0	0
BUN, Day 0, Normal [N=51,16,48,16]	47	14	43	13
BUN, Day 0, Above [N=51,16,48,16]	4	2	5	3
BUN, Day 21, Below [N=45,17,46,17]	0	0	0	0
BUN, Day 21, Normal [N=45,17,46,17]	38	14	43	15
BUN, Day 21, Above [N=45,17,46,17]	7	3	3	2
BUN, Day 42, Below [N=47,17,47,17]	0	0	0	0
BUN, Day 42, Normal [N=47,17,47,17]	40	14	43	14
BUN, Day 42, Above [N=47,17,47,17]	7	3	4	3
BUN, Month 6, Below [N=42,16,43,17]	0	0	0	0
BUN, Month 6, Normal [N=42,16,43,17]	42	13	43	17
BUN, Month 6, Above [N=42,16,43,17]	0	3	0	0
BUN, Month 12, Below [N=44,17,45,17]	0	0	0	0
BUN, Month 12, Normal [N=44,17,45,17]	39	15	44	14
BUN, Month 12, Above [N=44,17,45,17]	5	2	1	3
BUN, Month 24, Below [N=45,17,44,17]	0	0	0	0
BUN, Month 24, Normal [N=45,17,44,17]	40	13	41	16
BUN, Month 24, Above [N=45,17,44,17]	5	4	3	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Alanine Aminotransferase (ALT) in Study Phase C

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Alanine Aminotransferase (ALT) in Study Phase C[161][162]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents ALT results, for subjects participating to Phase C of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[161] - 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.
[162] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Alanine Aminotransferase (ALT)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	17	46	18
Units: Subjects				
ALT,Day 0,Below [N=44,15,46,17]	0	0	0	0
ALT, Day 0,Normal [N=44,15,46,17]	43	15	45	17
ALT,Day 0,Above [N=44,15,46,17]	1	0	1	0
ALT,Day 21,Below [N=45,12,42,18]	0	0	0	0
ALT,Day 21,Normal [N=45,12,42,18]	44	12	42	18
ALT,Day 21,Above [N=45,12,42,18]	1	0	0	0
ALT,Day 42,Below [N=46,16,46,18]	0	0	0	0
ALT,Day 42,Normal [N=46,16,46,18]	46	16	46	18
ALT,Day 42,Above [N=46,16,46,18]	0	0	0	0
ALT, Month 6, Below [N=41,16,44,18]	0	0	0	0
ALT, Month 6, Normal [N=41,16,44,18]	41	15	44	18
ALT, Month 6, Above [N=41,16,44,18]	0	1	0	0
ALT,Month12,Below [N=42,17,46,17]	0	0	0	0
ALT,Month 12,Normal [N=42,17,46,17]	42	17	44	17
ALT,Month 12,Above [N=42,17,46,17]	0	0	2	0
ALT,Month 24,Below [N=41,17,46,18]	0	0	0	0
ALT,Month 24,Normal [N=41,17,46,18]	39	17	44	18
ALT,Month 24,Above [N=41,17,46,18]	2	0	2	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatine Phosphokinase (CPK) in Study Phase B

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatine Phosphokinase (CPK) in Study Phase B[163][164]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents CPK results, for subjects participating to Phase B of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[163] - 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.
[164] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to Creatine Phosphokinase (CPK)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	48	17
Units: Subjects				
CPK, Day 0, Below [N=51,16,48,17]	0	0	0	0
CPK, Day 0, Normal [N=51,16,48,17]	49	16	46	16
CPK, Day 0, Above [N=51,16,48,17]	2	0	2	1
CPK, Day 21, Below [N=45,17,46,17]	0	0	0	0
CPK, Day 21, Normal [N=45,17,46,17]	42	16	45	16
CPK, Day 21, Above [N=45,17,46,17]	3	1	1	1
CPK, Day 42, Below [N=47,17,47,17]	0	0	0	0
CPK, Day 42, Normal [N=47,17,47,17]	43	15	44	16
CPK, Day 42, Above [N=47,17,47,17]	4	2	3	1
CPK, Month 6, Below [42,16,43,17]	0	0	0	0
CPK, Month 6, Normal [42,16,43,17]	40	13	41	15
CPK, Month 6, Above [42,16,43,17]	2	3	2	2
CPK, Month 12, Below [N=44,17,45,17]	0	0	0	0
CPK, Month 12, Normal [N=44,17,45,17]	39	14	44	17
CPK, Month 12, Above [N=44,17,45,17]	5	3	1	0
CPK, Month 24, Below [N=45,17,44,17]	0	0	0	0
CPK, Month 24, Normal [N=45,17,44,17]	44	15	42	16
CPK, Month 24, Above [N=45,17,44,17]	1	2	2	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Aspartate Aminotransferase (AST) in Study Phase C

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Respect to Aspartate Aminotransferase (AST) in Study Phase C[165][166]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents AST results, for subjects participating to Phase C of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[165] - 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.
[166] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status as Regards to the Biochemical Parameter Aspartate Aminotransferase (AST)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	17	46	18
Units: Subjects				
AST,Day 0,Below [N=44,15,46,17]	0	0	0	0
AST,Day 0,Normal [N=44,15,46,17	41	12	45	17
AST,Day 0,Above [N=44,15,46,17	3	3	1	0
AST, Day 21,Below [N=45,12,42,18]	0	0	0	0
AST,Day 21,Normal [N=45,12,42,18]	44	12	42	18
AST,Day 21,Above [N=45,12,42,18]	1	0	0	0
AST,Day 42,Below [N=46,16,46,18]	0	0	0	0
AST,Day 42,Normal [N=46,16,46,18]	44	14	43	18
AST,Day 42,Above [N=46,16,46,18]	2	2	3	0
AST,Month 6,Below [N=40,16,44,18]	0	0	0	0
AST, Month 6, Normal [N=40,16,44,18]	39	14	43	18
AST, Month 6, Above [N=40,16,44,18]	1	2	1	0
AST,Month 12,Below [N=41,17,45,17]	0	0	0	0
AST,Month 12,Normal [N=41,17,45,17]	41	17	40	17

AST,Month 12,Above [N=41,17,45,17]	0	0	5	0
AST,Month 24,Below [N=41,17,46,18]	0	0	0	0
AST,Month 24,Normal [N=41,17,46,18]	38	17	45	18
AST,Month 24,Above [N=41,17,46,18]	3	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatine Phosphokinase (CPK) in Study Phase C

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatine Phosphokinase (CPK) in Study Phase C[167][168]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents CPK results, for subjects participating to Phase C of the study.

End point type	Primary

End point timeframe:

At Days 0, 21, and 42, and at Months 6, 12 and 24

Notes:

[167] - 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.
[168] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to Creatine Phosphokinase (CPK)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	17	46	18
Units: Subjects				
CPK, Day 0, Below [N=44,15,46,17]	0	0	0	0
CPK, Day 0, Normal [N=44,15,46,17]	43	13	42	16
CPK, Day 0, Above [N=44,15,46,17]	1	2	4	1
CPK, Day 21, Below [N=45,12,42,18]	0	0	0	0
CPK, Day 21, Normal [N=45,12,42,18]	43	11	41	16
CPK, Day 21, Above [N=45,12,42,18]	2	1	1	2
CPK, Day 42, Below [N=46,16,46,18]	0	0	0	0
CPK, Day 42, Normal [N=46,16,46,18]	44	13	46	17
CPK, Day 42, Above [N=46,16,46,18]	2	3	0	1
CPK, Month 6, Below [N=41,16,44,18]	0	0	0	0
CPK, Month 6, Normal [N=41,16,44,18	37	15	41	18
CPK, Month 6, Above [N=41,16,44,18	4	1	3	0
CPK, Month 12, Below [N=42,17,46,17]	0	0	0	0

CPK, Month 12, Normal [N=42,17,46,17]	38	15	42	16
CPK, Month 12, Above [N=42,17,46,17]	4	2	4	1
CPK, Month 24, Below [N=41,17,46,18]	0	0	0	0
CPK, Month 24, Normal [N=41,17,46,18]	39	15	43	16
CPK, Month 24, Above [N=41,17,46,18]	2	2	3	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatinine (CREA) in Study Phase C

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Creatinine (CREA) in Study Phase C[169][170]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents CREA results, for subjects participating to Phase C of the study.

End point type	Primary

End point timeframe:

At Days 0, 21 and 42 and at Months 6, 12 and 24

Notes:

[169] - 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.
[170] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to the Biochemical Parameter Blood Creatinine (CREA)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	17	46	18
Units: Subjects				
CREA, Day 0, Below [N=44,15,46,17]	0	0	0	0
CREA, Day 0, Normal [N=44,15,46,17]	44	15	46	17
CREA, Day 0, Above [N=44,15,46,17]	0	0	0	0
CREA, Day 21, Below [N=45,12,42,18]	0	0	0	0
CREA, Day 21, Normal [N=45,12,42,18]	45	12	42	18
CREA, Day 21, Above [N=45,12,42,18]	0	0	0	0
CREA, Day 42, Below [N=46,16,46,18]	0	0	0	0
CREA, Day 42, Normal [N=46,16,46,18]	46	16	46	18
CREA, Day 42, Above [N=46,16,46,18]	0	0	0	0
CREA, Month 6, Below [N=41,16,44,18]	0	0	0	0

CREA, Month 6, Normal [N=41,16,44,18]	41	16	44	18
CREA, Month 6, Above [N=41,16,44,18]	0	0	0	0
CREA, Month 12, Below [N=42,17,46,17]	0	0	0	0
CREA, Month 12, Normal [N=42,17,46,17]	42	17	46	17
CREA, Month 12, Above [N=42,17,46,17]	0	0	0	0
CREA, Month 24, Below [N=41,17,46,18]	0	0	0	0
CREA, Month 24, Normal [N=41,17,46,18]	41	17	46	18
CREA, Month 24, Above [N=41,17,46,18]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Lactate Dehydrogenase (LDH) in Study Phase C

End point title	Number of Subjects With Normal and Abnormal Biochemical Parameters Assessed With Regards to Lactate Dehydrogenase (LDH) in Study Phase C[171][172]

End point description:

Assessed biochemical parameters were alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine (CREA), blood urea nitrogen (BUN), lactate dehydrogenase (LDH), and creatine phosphokinase (CPK). Per parameter , it was assessed whether subjects had laboratory values below normal, normal, or above normal range. This outcome presents LDH results, for subjects participating to Phase C of the study.

End point type	Primary

End point timeframe:

At Days 0, 21 and 42 and at Months 6, 12 and 24

Notes:

[171] - 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.
[172] - 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: There are 3 tables corresponding to the endpoint (Number of Subjects With Changed Status With Regards to Lactate Dehydrogenase (LDH)), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	17	47	18
Units: Subjects				
LDH, Day 0, Below [N=44,15,47,17]	0	0	0	0
LDH, Day 0, Normal [N=44,15,47,17]	36	12	44	17
LDH, Day 0, Above [N=44,15,47,17]	8	3	3	0
LDH, Day 21, Below [N=45,12,42,18]	0	0	0	0

LDH, Day 21, Normal [N=45,12,42,18]	38	11	39	17
LDH, Day 21, Above [N=45,12,42,18]	7	1	3	1
LDH, Day 42, Below [N=46,16,46,18]	0	0	0	0
LDH, Day 42, Normal [N=46,16,46,18]	35	8	42	17
LDH, Day 42, Above [N=46,16,46,18]	11	8	4	1
LDH, Month 6, Below [N=40,16,44,18]	0	0	0	0
LDH, Month 6, Normal [N=40,16,44,18]	32	10	40	18
LDH, Month 6, Above [N=40,16,44,18]	8	6	4	0
LDH, Month 12, Below [N=41,17,45,17]	0	0	0	0
LDH, Month 12, Normal [N=41,17,45,17]	30	12	36	15
LDH, Month 12, Above [N=41,17,45,17]	11	5	9	2
LDH, Month 24, Below [N=41,17,46,18]	0	0	0	0
LDH, Month 24, Normal [N=41,17,46,18]	28	14	43	17
LDH, Month 24, Above [N=41,17,46,18]	13	3	3	1

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease

End point title	Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease[173]

End point description:

Titers of serum neutralizing antibodies are presented as geometric mean titers (GMTs). The cut-off of the assay was the seropositivity cut-off value of 1:28. The influenza strain assessed was A/Vietnam/1194/04 (A/VIET).Results presented are for subjects participating in Phase A of the study

End point type	Secondary

End point timeframe:

At Days 0, 21 and 42

Notes:

[173] - 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: There are 3 tables corresponding to the endpoint (Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	15	43	15
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET, Day 0 [N=47,14,43,15]	31 (21.8 to 44)	29 (15.2 to 55.2)	32.2 (23.1 to 44.9)	18.2 (12.2 to 27.3)
A/VIET, Day 21 [N=48,15,43,14]	173.5 (123.3 to 244)	98.2 (52.4 to 184.1)	177.5 (127 to 248)	97.2 (46.3 to 204)
A/VIET, Day 42 [N=47,15,42,15]	1044.4 (845.4 to 1290.3)	158.4 (76.5 to 327.8)	1155.1 (920.9 to 1448.7)	104.5 (51.2 to 213.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease

End point title	Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease[174]

End point description:

Titers of serum neutralizing antibodies are presented as geometric mean titers (GMTs). The cut-off of the assay was the seropositivity cut-off value of 1:28. The influenza strain assessed was A/Vietnam/1194/04 (A/VIET). Results presented are for subjects participating in Phase B of the study.

End point type	Secondary

End point timeframe:

At Days 0, 21 and 42

Notes:

[174] - 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: There are 3 tables corresponding to the endpoint (Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	16	45	17
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET, Day 0 [N=42,16,45,17]	65.5 (47.3 to 90.7)	48.8 (29.7 to 80.2)	46.2 (33.2 to 64.2)	25.6 (17.3 to 37.8)
A/VIET, Day 21[N=39,16,45,17]	344.7 (260.9 to 455.3)	124.9 (60.7 to 257.2)	461.7 (376.2 to 566.5)	148.3 (81.2 to 271.1)
A/VIET, Day 42 [N=42,16,45,17]	1553.2 (1105.9 to 2181.5)	86.9 (42.5 to 177.6)	1519.4 (1229.9 to 1877)	154.6 (97.9 to 244)

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease

End point title	Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease[175]

End point description:

Titers of serum neutralizing antibodies are presented as geometric mean titers (GMTs). The cut-off of the assay was the seropositivity cut-off value of 1:28. The influenza strain assessed was A/Vietnam/1194/04 (A/VIET). Results presented are for subjects participating in Phase C of the study.

End point type	Secondary

End point timeframe:

At Days 0, 21 and 42

Notes:

[175] - 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: There are 3 tables corresponding to the endpoint (Titers for Serum Neutralizing Antibodies Against 1 Strain of Influenza Disease), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	15	43	13
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET, Day 0 [N=40,15,43,13]	37.3 (23.9 to 58.1)	35.5 (17.3 to 72.8)	25.6 (18.6 to 35.3)	27.1 (13.3 to 55.4)
A/VIET, Day 21 [N=40,15,29,8]	473.8 (351.2 to 639.3)	111.3 (52.7 to 234.9)	313.5 (193.3 to 508.4)	190.1 (57.6 to 628.2)
A/VIET, Day 42 [N=42,14,42,13]	4578.3 (3786.6 to 5535.6)	102.3 (45.9 to 228.2)	3032.5 (2431.8 to 3781.6)	77.6 (31.3 to 192.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies

End point title	Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies[176]

End point description:

A seroconverted subject as regards to serum neutralizing antibodies against influenza disease was a subject with a minimum 4-fold increase in serum neutralizing antibody titer at post-vaccination. The flu strain assessed was A/Vietnam/1194/2004 (A/VIET). This outcome presents results for subjects participating to Phase A of the study.

End point type	Secondary

End point timeframe:

At Days 21 and 42

Notes:

[176] - 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: There are 3 tables corresponding to the endpoint (Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	14	43	15
Units: Subjects				
A/VIET, Day 21 [N=46,14,43,14]	31	6	28	10
A/VIET, Day 42 [N=45,14,42,15]	43	8	42	10

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies

End point title	Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies[177]

End point description:

A seroconverted subject as regards to serum neutralizing antibodies against influenza disease was a subject with a minimum 4-fold increase in serum neutralizing antibody titer at post-vaccination. The flu strain assessed was A/Vietnam/1194/2004 (A/VIET). This outcome presents results for subjects participating to Phase C of the study.

End point type	Secondary

End point timeframe:

At Days 21 and 42

Notes:

[177] - 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: There are 3 tables corresponding to the endpoint (Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	15	42	13
Units: Subjects				
A/VIET, Day 21 [N=36,15,29,8]	29	7	23	3
A/VIET, Day 42 [N=38,14,42,13]	37	6	42	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies

End point title	Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies[178]

End point description:

A seroconverted subject as regards to serum neutralizing antibodies against influenza disease was a subject with a minimum 4-fold increase in serum neutralizing antibody titer at post-vaccination. The flu strain assessed was A/Vietnam/1194/2004 (A/VIET). This outcome presents results for subjects participating to Phase B of the study.

End point type	Secondary

End point timeframe:

At Days 21 and 42

Notes:

[178] - 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: There are 3 tables corresponding to the endpoint (Number of Seroconverted Subjects Against One Strain of Influenza Disease With Respect to Serum Neutralizing Antibodies), each table representing the result by Phase and the corresponding arms for that phase.

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	16	45	17
Units: Subjects				
A/VIET, Day 21 [N=39,16,45,17]	25	6	35	11
A/VIET, Day 42 [N=42,16,45,17]	40	2	42	11

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Seroconverted Subjects Against 2 Strains of Influenza Disease as Regards to Neutralizing Antibody Response

End point title	Number of Seroconverted Subjects Against 2 Strains of Influenza Disease as Regards to Neutralizing Antibody Response[179]

End point description:

A seroconverted subject as regards to neutralizing antibody response was a subject with a minimum 4-fold increase in neutralizing antibody titer at post-vaccination. The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO) strains. Results presented are for subjects participating in Phase A of the study. Subjects participating to Phases B and C of the study were not analysed at these persistence time points for this outcome.

End point type	Secondary

End point timeframe:

At Months 6, 12 and 24.

Notes:

[179] - 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 participating to Phases B and C of the study were not analysed at these persistence time points for this outcome.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	13	40	14
Units: Subjects				
A/VIET, Month 6 [N=47,13,40,14]	41	9	38	13
A/VIET, Month 12 [N=45,13,34,14]	37	3	23	3
A/VIET, Month 24 [N=45,12,36,11	36	3	23	4
A/INDO, Month 6 [N=39,12,35,11]	34	0	31	1
A/INDO, Month 12 [N=43;13;34;14]	37	1	31	2
A/INDO, Month 24 [N=43;12;36;11]	40	3	33	2

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for Serum Neutralizing Antibodies Against 2 Strains of Influenza Disease

End point title	Titers for Serum Neutralizing Antibodies Against 2 Strains of Influenza Disease[180]

End point description:

Titers of serum neutralizing antibodies are presented as geometric mean titers (GMTs). The cut-off of the assay was the seropositivity cut-off value of 1:28. The 2 influenza strains assessed were A/Vietnam/1194/04 (A/VIET) and A/Indonesia/05/2005 (A/INDO) strains. Results presented are for subjects participating in Phase A of the study. Subjects participating to Phases B and C of the study were not analysed at these persistence time points for this outcome.

End point type	Secondary

End point timeframe:

At Months 6, 12 and 24

Notes:

[180] - 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 participating to Phases B and C of the study were not analysed at these persistence time points for this outcome.

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	14	40	14
Units: units: Titer				
geometric mean (confidence interval 95%)				
A/VIET, Month 6 [N=49,14,40,14]	781.2 (641.5 to 951.5)	208.5 (108.6 to 400.3)	756.1 (624.5 to 915.5)	482.3 (313.4 to 742.3)
A/VIET, Month 12 [N=47,14,36,14]	238.9 (186.1 to 306.6)	35.4 (16.7 to 74.9)	179.4 (126.1 to 255.3)	27.6 (13.4 to 56.9)
A/VIET, Month 24 [N=47,13,38,11]	302.5 (231 to 396)	39.4 (16.3 to 95.5)	234.5 (177.1 to 310.6)	46.6 (18.4 to 118.3)
A/INDO, Month 6 [N=43,13,37,11]	113.8 (87.2 to 148.6)	17 (11.1 to 26.1)	106.8 (82.6 to 138)	16.9 (11.1 to 25.8)
A/INDO, Month 12 [N=47,14,36,14]	170.8 (132.7 to 220)	18.2 (11.4 to 29.1)	139.7 (105.8 to 184.6)	21.9 (12.2 to 39.2)

A/INDO, Month 24 [N=47,13,38,11]	188.5 (144.6 to 245.7)	31.8 (14.6 to 69.3)	146 (111.7 to 190.8)	20.5 (11.6 to 36.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Adverse Events of Specific Interest (AESIs)

End point title	Number of Subjects With Adverse Events of Specific Interest (AESIs)

End point description:

AESIs are adverse events such as clearly autoimmune diseases and also other inflammatory and/or neurologic disorders which may or may not have an autoimmune etiology. AESIs assessed included neuroinflammatory disorders such as cranial nerve disorders, multiple sclerosis,transverse myelitis, Guillain-Barré syndromeor neuritis), musculoskeletal disorders (such as systemic lupus erythematosus, cutaneous lupus, polymyositis, rheumatoid arthritis, reactive arthritis, psoriatic arthropathy, or undifferentiated spondyloarthropathy), gastrointestinal disorders (such as Crohn's disease, ulcerative colitis, ulcerative proctitis, celiac disease), metabolic diseases (such as autoimmune thyroiditis, Addison's disease). skin disorders (such as psoriasis, vitiligo, Raynaud's phenomenon, or autoimmune bullous skin diseases), and other conditions as autoimmune hemolytic anemia, thrombocytopenias, antiphospholipid syndrome, vasculitis, autoimmune hepatitis, or sarcoidosis.

End point type	Secondary

End point timeframe:

Throughout the entire study period, from Day 0 to Month 24

End point values	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A –A Lot 1 6-9Y Group	Fluarix–A 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	18	51	18
Units: Subjects	1	0	0	1

End point values	GSK1562902A –B Lot 2 3-5Y Group	Fluarix–B 3-5Y Group	GSK1562902A –B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	17	49	17
Units: Subjects	1	1	0	0

End point values	GSK1562902A –C Lot 3 3-5Y Group	Fluarix–C 3-5Y Group	GSK1562902A –C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	17	49	18
Units: Subjects	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs): from Day 0 to Month 24. Unsolicited adverse events (AEs): during the 21-days period post Dose 1 on Day 0 or the 30-days period post Dose 2 on Day 42. Solicited local and general symptoms: within 7 days post any vaccination.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13

Reporting groups

Reporting group title	GSK1562902A –A Lot 1 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 1. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–A 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–A Lot 1 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 1. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–B Lot 2 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 2. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–A 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase A of this NCT00502593 study (or study 107066). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–B 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–B Lot 2 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 2. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–B 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase B of this NCT00502593 study (or study 108498). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–C Lot 3 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of GSK1562902A vaccine, lot 3. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The GSK1562902A vaccine was

administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–C 3-5Y Group

Reporting group description:

Subjects aged 3-5 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	GSK1562902A–C Lot 3 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of GSK1562902A vaccine, lot 3. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The GSK1562902A vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Reporting group title	Fluarix–C 6-9Y Group

Reporting group description:

Subjects aged 6-9 years received 2 doses of Fluarix vaccine. These subjects were enrolled in the Phase C of this NCT00502593 study (or study 108500). The Fluarix vaccine was administered intramuscularly in the deltoid region of the non-dominant arm on Days 0 and 21.

Serious adverse events	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A–A Lot 1 6-9Y Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Transaminases increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (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
Injury, poisoning and procedural complications			
Wound			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (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
Traumatic brain injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (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
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (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
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK1562902A–B Lot 2 3-5Y Group	Fluarix–A 6-9Y Group	Fluarix–B 3-5Y Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 51 (1.96%)	0 / 18 (0.00%)	1 / 17 (5.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Transaminases increased			
subjects affected / exposed	1 / 51 (1.96%)	0 / 18 (0.00%)	0 / 17 (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
Injury, poisoning and procedural complications			
Wound			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Traumatic brain injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	1 / 51 (1.96%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
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	GSK1562902A–B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group	GSK1562902A–C Lot 3 3-5Y Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	2 / 49 (4.08%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Transaminases increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (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
Injury, poisoning and procedural complications			
Wound			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (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
Traumatic brain injury			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Fluarix–C 3-5Y Group	GSK1562902A–C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)	1 / 49 (2.04%)	0 / 18 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Transaminases increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (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
Injury, poisoning and procedural complications			
Wound			
subjects affected / exposed	0 / 17 (0.00%)	1 / 49 (2.04%)	0 / 18 (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
Traumatic brain injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (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
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (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
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (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

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

Non-serious adverse events	GSK1562902A –A Lot 1 3-5Y Group	Fluarix–A 3-5Y Group	GSK1562902A–A Lot 1 6-9Y Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 51 (60.78%)	7 / 18 (38.89%)	44 / 51 (86.27%)
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tooth injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Contusion			

subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 51 (17.65%)	3 / 18 (16.67%)	3 / 51 (5.88%)
occurrences (all)	9	3	3
Induration			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 51 (13.73%)	1 / 18 (5.56%)	12 / 51 (23.53%)
occurrences (all)	7	1	12
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	31 / 51 (60.78%)	7 / 18 (38.89%)	44 / 51 (86.27%)
occurrences (all)	31	7	44
Redness			

alternative assessment type: Systematic			
subjects affected / exposed	10 / 51 (19.61%)	2 / 18 (11.11%)	12 / 51 (23.53%)
occurrences (all)	10	2	12
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 51 (19.61%)	1 / 18 (5.56%)	14 / 51 (27.45%)
occurrences (all)	10	1	14
Drowsiness (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 51 (13.73%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	7	1	0
Fever (axillary temperature >=37.5° C) (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 51 (15.69%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	8	0	0
Irritability (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 51 (17.65%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	9	1	0
Loss of appetite (Symptom assessed in subjects aged 3-5 years.)			
subjects affected / exposed	12 / 51 (23.53%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	12	1	0
Shivering (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 51 (1.96%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Sweating (Symptom assessed in subjects aged 3-5 years)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 51 (7.84%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	4	0	0
Vomiting (Symptom assessed in subjects aged 3-5 years)			

subjects affected / exposed	7 / 51 (13.73%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	7	0	0
Arthralgia (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	6 / 51 (11.76%)
occurrences (all)	0	0	6
Fatigue (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	7 / 51 (13.73%)
occurrences (all)	0	0	7
Fever (axillary temperature >= 37.5°C) (Symptom assessed in subjects aged 6-9 years.)			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	7 / 51 (13.73%)
occurrences (all)	0	0	7
Gastrointestinal symptoms (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	9 / 51 (17.65%)
occurrences (all)	0	0	9
Headache (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	20 / 51 (39.22%)
occurrences (all)	0	0	20
Myalgia	Additional description: Symptom assessed in subjects aged 6-9 years		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	10 / 51 (19.61%)
occurrences (all)	0	0	10
Shivering	Additional description: Symptom assessed in subjects aged 6-9 years.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	3 / 51 (5.88%)
occurrences (all)	0	0	3
Sweating	Additional description: Symptom assessed in subjects aged 6-9 years.		
alternative assessment type: Systematic			

subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	3 / 51 (5.88%)
occurrences (all)	0	0	3
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	1 / 51 (1.96%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 51 (11.76%)	5 / 18 (27.78%)	0 / 51 (0.00%)
occurrences (all)	6	5	0
Rhinorrhoea			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Herpangina			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bronchitis chronic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Acne			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Tic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Torticollis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Pharyngitis			
subjects affected / exposed	3 / 51 (5.88%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	3	0	0
Upper respiratory tract infection			
subjects affected / exposed	11 / 51 (21.57%)	3 / 18 (16.67%)	2 / 51 (3.92%)
occurrences (all)	11	3	2
Bronchitis			
subjects affected / exposed	2 / 51 (3.92%)	2 / 18 (11.11%)	0 / 51 (0.00%)
occurrences (all)	2	2	0
Folliculitis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	5 / 51 (9.80%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	5	1	0
Impetigo			
subjects affected / exposed	1 / 51 (1.96%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Myringitis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Scarlet fever			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	3 / 51 (5.88%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	3	0	0
Otitis media acute			
subjects affected / exposed	3 / 51 (5.88%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	3	0	0
Varicella			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Tooth abscess			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	GSK1562902A–B Lot 2 3-5Y Group	Fluarix–A 6-9Y Group	Fluarix–B 3-5Y Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 51 (52.94%)	12 / 18 (66.67%)	4 / 17 (23.53%)
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tooth injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Injection site reaction			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 51 (7.84%)	2 / 18 (11.11%)	0 / 17 (0.00%)
occurrences (all)	4	2	0
Induration			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 51 (7.84%)	6 / 18 (33.33%)	1 / 17 (5.88%)
occurrences (all)	4	6	1
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	27 / 51 (52.94%)	12 / 18 (66.67%)	3 / 17 (17.65%)
occurrences (all)	27	12	3
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 51 (11.76%)	5 / 18 (27.78%)	4 / 17 (23.53%)
occurrences (all)	6	5	4
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 51 (17.65%)	7 / 18 (38.89%)	2 / 17 (11.76%)
occurrences (all)	9	7	2
Drowsiness (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 51 (17.65%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	9	0	1
Fever (axillary temperature >=37.5° C) (Symptom assessed in subjects aged 3-5 years.)			

alternative assessment type: Systematic			
subjects affected / exposed	10 / 51 (19.61%)	0 / 18 (0.00%)	2 / 17 (11.76%)
occurrences (all)	10	0	2
Irritability (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 51 (25.49%)	0 / 18 (0.00%)	2 / 17 (11.76%)
occurrences (all)	13	0	2
Loss of appetite (Symptom assessed in subjects aged 3-5 years.)			
subjects affected / exposed	8 / 51 (15.69%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	8	0	1
Shivering (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 51 (7.84%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	4	0	1
Sweating (Symptom assessed in subjects aged 3-5 years)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 51 (1.96%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Vomiting (Symptom assessed in subjects aged 3-5 years)			
subjects affected / exposed	6 / 51 (11.76%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	6	0	0
Arthralgia (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	3 / 18 (16.67%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Fatigue (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Fever (axillary temperature >= 37.5°C) (Symptom assessed in subjects aged 6-9 years.)			

subjects affected / exposed	0 / 51 (0.00%)	3 / 18 (16.67%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal symptoms (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	5 / 18 (27.78%)	0 / 17 (0.00%)
occurrences (all)	0	5	0
Headache (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	5 / 18 (27.78%)	0 / 17 (0.00%)
occurrences (all)	0	5	0
Myalgia	Additional description: Symptom assessed in subjects aged 6-9 years		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	3 / 18 (16.67%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Shivering	Additional description: Symptom assessed in subjects aged 6-9 years.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Sweating	Additional description: Symptom assessed in subjects aged 6-9 years.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 51 (0.00%)	2 / 18 (11.11%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 51 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	3 / 51 (5.88%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	3	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 51 (5.88%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	3	0	0
Bronchitis chronic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Acne			

subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pityriasis rosea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Tic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Torticollis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Pharyngitis			
subjects affected / exposed	6 / 51 (11.76%)	2 / 18 (11.11%)	2 / 17 (11.76%)
occurrences (all)	6	2	2
Upper respiratory tract infection			
subjects affected / exposed	4 / 51 (7.84%)	1 / 18 (5.56%)	1 / 17 (5.88%)
occurrences (all)	4	1	1
Bronchitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	3 / 17 (17.65%)
occurrences (all)	0	0	3
Impetigo			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Myringitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Acute tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	2 / 51 (3.92%)	0 / 18 (0.00%)	3 / 17 (17.65%)
occurrences (all)	2	0	3
Otitis media acute			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	1 / 51 (1.96%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Tooth abscess			
subjects affected / exposed	0 / 51 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	GSK1562902A–B Lot 2 6-9Y Group	Fluarix–B 6-9Y Group	GSK1562902A–C Lot 3 3-5Y Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 49 (73.47%)	9 / 17 (52.94%)	37 / 49 (75.51%)
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			

subjects affected / exposed	0 / 49 (0.00%)	1 / 17 (5.88%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tooth injury			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	3 / 49 (6.12%)
occurrences (all)	0	0	3
Dizziness			
subjects affected / exposed	0 / 49 (0.00%)	1 / 17 (5.88%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 17 (5.88%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
alternative assessment type: Systematic			

subjects affected / exposed	4 / 49 (8.16%)	1 / 17 (5.88%)	4 / 49 (8.16%)
occurrences (all)	4	1	4
Induration			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 49 (12.24%)	1 / 17 (5.88%)	14 / 49 (28.57%)
occurrences (all)	6	1	14
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	36 / 49 (73.47%)	9 / 17 (52.94%)	37 / 49 (75.51%)
occurrences (all)	36	9	37
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 49 (12.24%)	3 / 17 (17.65%)	16 / 49 (32.65%)
occurrences (all)	6	3	16
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 49 (20.41%)	2 / 17 (11.76%)	18 / 49 (36.73%)
occurrences (all)	10	2	18
Drowsiness (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	12 / 49 (24.49%)
occurrences (all)	0	0	12
Fever (axillary temperature >=37.5° C) (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	18 / 49 (36.73%)
occurrences (all)	0	0	18
Irritability (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	18 / 49 (36.73%)
occurrences (all)	0	0	18
Loss of appetite (Symptom assessed in subjects aged 3-5 years.)			

subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	15 / 49 (30.61%)
occurrences (all)	0	0	15
Shivering (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	10 / 49 (20.41%)
occurrences (all)	0	0	10
Sweating (Symptom assessed in subjects aged 3-5 years)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	4 / 49 (8.16%)
occurrences (all)	0	0	4
Vomiting (Symptom assessed in subjects aged 3-5 years)			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	6 / 49 (12.24%)
occurrences (all)	0	0	6
Arthralgia (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 49 (14.29%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	7	0	0
Fatigue (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 49 (12.24%)	1 / 17 (5.88%)	0 / 49 (0.00%)
occurrences (all)	6	1	0
Fever (axillary temperature >= 37.5°C) (Symptom assessed in subjects aged 6-9 years.)			
subjects affected / exposed	3 / 49 (6.12%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	3	0	0
Gastrointestinal symptoms (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 49 (8.16%)	5 / 17 (29.41%)	0 / 49 (0.00%)
occurrences (all)	4	5	0
Headache (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			

subjects affected / exposed	11 / 49 (22.45%)	2 / 17 (11.76%)	0 / 49 (0.00%)
occurrences (all)	11	2	0
Myalgia	Additional description: Symptom assessed in subjects aged 6-9 years		
alternative assessment type: Systematic			
subjects affected / exposed	11 / 49 (22.45%)	2 / 17 (11.76%)	0 / 49 (0.00%)
occurrences (all)	11	2	0
Shivering	Additional description: Symptom assessed in subjects aged 6-9 years.		
alternative assessment type: Systematic			
subjects affected / exposed	7 / 49 (14.29%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	7	0	0
Sweating	Additional description: Symptom assessed in subjects aged 6-9 years.		
alternative assessment type: Systematic			
subjects affected / exposed	3 / 49 (6.12%)	2 / 17 (11.76%)	0 / 49 (0.00%)
occurrences (all)	3	2	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 17 (5.88%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bronchitis chronic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Tic			

subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Torticollis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Pharyngitis			
subjects affected / exposed	3 / 49 (6.12%)	0 / 17 (0.00%)	3 / 49 (6.12%)
occurrences (all)	3	0	3
Upper respiratory tract infection			
subjects affected / exposed	3 / 49 (6.12%)	0 / 17 (0.00%)	10 / 49 (20.41%)
occurrences (all)	3	0	10
Bronchitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Myringitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			

subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 17 (5.88%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 17 (5.88%)	4 / 49 (8.16%)
occurrences (all)	0	1	4
Otitis media acute			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 49 (0.00%)	0 / 17 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Fluarix–C 3-5Y Group	GSK1562902A–C Lot 3 6-9Y Group	Fluarix–C 6-9Y Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 17 (41.18%)	44 / 49 (89.80%)	15 / 18 (83.33%)
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tooth injury			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Contusion			

subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Fibula fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 17 (0.00%)	3 / 49 (6.12%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Ecchymosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Induration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	10 / 49 (20.41%)	1 / 18 (5.56%)
occurrences (all)	0	10	1
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 17 (41.18%)	44 / 49 (89.80%)	15 / 18 (83.33%)
occurrences (all)	7	44	15
Redness			

alternative assessment type: Systematic			
subjects affected / exposed	2 / 17 (11.76%)	6 / 49 (12.24%)	1 / 18 (5.56%)
occurrences (all)	2	6	1
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 17 (11.76%)	14 / 49 (28.57%)	3 / 18 (16.67%)
occurrences (all)	2	14	3
Drowsiness (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Fever (axillary temperature >=37.5° C) (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Irritability (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Loss of appetite (Symptom assessed in subjects aged 3-5 years.)			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Shivering (Symptom assessed in subjects aged 3-5 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Sweating (Symptom assessed in subjects aged 3-5 years)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vomiting (Symptom assessed in subjects aged 3-5 years)			

subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Arthralgia (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	9 / 49 (18.37%)	2 / 18 (11.11%)
occurrences (all)	0	9	2
Fatigue (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	11 / 49 (22.45%)	2 / 18 (11.11%)
occurrences (all)	0	11	2
Fever (axillary temperature >= 37.5°C) (Symptom assessed in subjects aged 6-9 years.)			
subjects affected / exposed	0 / 17 (0.00%)	18 / 49 (36.73%)	0 / 18 (0.00%)
occurrences (all)	0	18	0
Gastrointestinal symptoms (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	16 / 49 (32.65%)	5 / 18 (27.78%)
occurrences (all)	0	16	5
Headache (Symptom assessed in subjects aged 6-9 years.)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	25 / 49 (51.02%)	3 / 18 (16.67%)
occurrences (all)	0	25	3
Myalgia	Additional description: Symptom assessed in subjects aged 6-9 years		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	13 / 49 (26.53%)	2 / 18 (11.11%)
occurrences (all)	0	13	2
Shivering	Additional description: Symptom assessed in subjects aged 6-9 years.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	13 / 49 (26.53%)	3 / 18 (16.67%)
occurrences (all)	0	13	3
Sweating	Additional description: Symptom assessed in subjects aged 6-9 years.		
alternative assessment type: Systematic			

subjects affected / exposed	0 / 17 (0.00%)	6 / 49 (12.24%)	1 / 18 (5.56%)
occurrences (all)	0	6	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 17 (0.00%)	4 / 49 (8.16%)	0 / 18 (0.00%)
occurrences (all)	0	4	0
Rhinorrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bronchitis chronic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Acne			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Psychiatric disorders			
Tic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Torticollis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Infections and infestations			

Pharyngitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 49 (2.04%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 17 (11.76%)	6 / 49 (12.24%)	1 / 18 (5.56%)
occurrences (all)	2	6	1
Bronchitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 17 (0.00%)	3 / 49 (6.12%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Impetigo			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Myringitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	2 / 17 (11.76%)	3 / 49 (6.12%)	1 / 18 (5.56%)
occurrences (all)	2	3	1
Otitis media acute			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 17 (0.00%)	0 / 49 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Tooth abscess subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 49 (0.00%) 0	1 / 18 (5.56%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 February 2007	Amendment 1: Amendment of the study design to include additional age stratification steps with a safety review, following comments by the Medical Research and Ethics Committee (MREC).
17 April 2007	Amendment 2: Amendment to distinguish the internal and external safety review process. Inclusion of a description of biochemical analyses.
30 October 2007	Amendment 3: Amendment to extend the safety follow-up period to 2 years after the first vaccination.
25 February 2009	Amendment 4: Amendment to exclude the neutralizing antibodies analysis (secondary endpoints) for Phase B (study H5N1-022 STG 009 cohort 2) and Phase C (H5N1-023 STG 009 cohort 3). Additionally, recording of AESIs (adverse events of specific interest) for influenza vaccines will be done in a retrospective manner (Day 0-Month 24).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported