Clinical trial results:
A phase III, randomized, open, active-controlled study to evaluate the safety and immunogenicity of a prime-boost schedule of the H5N1 candidate vaccine adjuvanted with AS03B administered to children aged 3 to 17 years.

Summary

EudraCT number	2011-004751-39
Trial protocol	Outside EU/EEA
Global end of trial date	05 October 2012

Results information

Result version number	v1
This version publication date	20 April 2016
First version publication date	24 May 2015

Trial information

Trial identification

Sponsor protocol code	115115

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01379937
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium,
Public contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000160-PIP01-07
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	05 October 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 October 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Co-primary Immunogenicity Objective

- To assess the superiority of the haemagglutination inhibition (HI) antibody response against A/turkey/Turkey/01/2005 (H5N1) 10 days following H5N1 vaccination at Day 182 [1.9 µg A/turkey/Turkey/01/2005 (H5N1) HA antigen adjuvanted with AS03B] in subjects previously primed with 2 doses of heterologous A/Indonesia/5/2005 (H5N1) vaccine (Group H5N1_H5N1) versus non primed subjects (Group Havrix_H5N1).

Co-primary Safety Objective

- To evaluate the safety of the paediatric H5N1 vaccine when administered as a 2-dose primary vaccination to subjects 3 to 17 years of age in terms of occurrence of medically attended adverse events (MAEs) from Day 0 to Day 182 and to the Day 364 visit.

Protection of trial subjects:

All subjects were supervised for 30 min after vaccination administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 July 2011
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	Philippines: 520
Worldwide total number of subjects	520
EEA total number of subjects	0

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)	320
Adolescents (12-17 years)	200
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was of an overall duration 364 days for all subjects.

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 Formulation 1 and 2 - Havrix / Havrix Jr Group

Arm description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, a booster vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 dose of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Arm type	Experimental
Investigational medicinal product name	H5N1 A/Indonesia/5/2005 with AS03B (Formulation 1)
Investigational medicinal product code	GSK1562902A
Other name	
Pharmaceutical forms	Emulsion and suspension for emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, two doses each in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group

Investigational medicinal product name	H5N1 A/turkey/Turkey/01/2005 with AS03B (Formulation 2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion and suspension for emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose each in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group

Investigational medicinal product name	Havrix 1440 Adult
Investigational medicinal product code	
Other name	Havrix™
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

Investigational medicinal product name	Havrix 720 Junior
Investigational medicinal product code	
Other name	Havrix™ Junior
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group,GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

Arm title	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group

Arm description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Arm type	Experimental
Investigational medicinal product name	H5N1 A/Indonesia/05/2005 with AS03B (Formulation 1)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion and suspension for emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, two doses each in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group

Investigational medicinal product name	Havrix 1440 Adult
Investigational medicinal product code	
Other name	Havrix™
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

Investigational medicinal product name	Havrix 720 Junior
Investigational medicinal product code	
Other name	Havrix™ Junior
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group,GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

Arm title	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group

Arm description:

Subjects in this group received 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Arm type	Active comparator
Investigational medicinal product name	H5N1 A/turkey/Turkey/01/2005 with AS03B (Formulation 2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion and suspension for emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose each in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group

Investigational medicinal product name	Havrix 1440 Adult
Investigational medicinal product code	
Other name	Havrix™

Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

Investigational medicinal product name	Havrix 720 Junior
Investigational medicinal product code	
Other name	Havrix™ Junior
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group,GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

Arm title	Havrix / Havrix Jr Group

Arm description:

Subjects in this group received 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Arm type	Active comparator
Investigational medicinal product name	Havrix 1440 Adult
Investigational medicinal product code	
Other name	Havrix™
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

Investigational medicinal product name	Havrix 720 Junior
Investigational medicinal product code	
Other name	Havrix™ Junior
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group,GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

Number of subjects in period 1	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group
Started	156	156	104
Completed	155	153	102
Not completed	1	3	2
Consent withdrawn by subject	-	1	-
Protocol violation	-	-	-
Migrated/moved from study area	1	2	2

Number of subjects in period 1	Havrix / Havrix Jr Group
Started	104
Completed	103
Not completed	1
Consent withdrawn by subject	-
Protocol violation	1
Migrated/moved from study area	-

Baseline characteristics

Reporting groups	
Reporting group title	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group
Reporting group description:	
Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, a booster vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 dose of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.	
Reporting group title	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group
Reporting group description:	
Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.	
Reporting group title	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group
Reporting group description:	
Subjects in this group received 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.	
Reporting group title	Havrix / Havrix Jr Group
Reporting group description:	
Subjects in this group received 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.	

Reporting group values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group
Number of subjects	156	156	104
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
geometric mean	9.7	9.4	9.3
standard deviation	± 4.26	± 3.88	± 3.87
Gender categorical			
Units: Subjects			
Female	81	81	52
Male	75	75	52

Reporting group values	Havrix / Havrix Jr Group	Total	
Number of subjects	104	520	

Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
geometric mean	9.6		
standard deviation	± 4.23	-	
Gender categorical Units: Subjects			
Female	52	266	
Male	52	254	

End points

End points reporting groups

Reporting group title	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group

Reporting group description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, a booster vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 dose of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Reporting group title	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group

Reporting group description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Reporting group title	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group

Reporting group description:

Subjects in this group received 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Reporting group title	Havrix / Havrix Jr Group

Reporting group description:

Subjects in this group received 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Subject analysis set title	GSK1562902A Formulation 1 & 2 - Havrix/Havrix Jr pooled Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Pooled group of subjects who received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, no or 1 booster dose of vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 or 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Subject analysis set title	GSK1562902A Formulation 2 - Havrix/Havrix Jr pooled Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Pooled group of subjects who received no or 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Primary: Haemagglutination Inhibition (HI) antibody titers for the A/Turkey/Turkey/01/2005 (H5N1) vaccine strain.

End point title	Haemagglutination Inhibition (HI) antibody titers for the A/Turkey/Turkey/01/2005 (H5N1) vaccine strain.[1]

End point description:

Antibody titers were expressed as Geometric mean titers (GMTs). The H5N1 vaccine strain included A/Turkey/Turkey/01/2005 antigen. The A/Turkey/Turkey/01/2005 (A/TURK) vaccine strain was administered to groups receiving the adjuvanted Influenza vaccine GSK1562902A. This outcome concerns solely subjects in the GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

End point type	Primary

End point timeframe:

At Day 192.

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was made only on subjects receiving A/turkey/Turkey/01/2005 strain containing vaccine..

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	84		
Units: Titer				
geometric mean (confidence interval 95%)				
Haemagglutination Inhibition (HI) antibody titers	737.6 (646.8 to 841.1)	24.7 (19.7 to 31)		

Statistical analyses

Statistical analysis title	Titer superiority of primed vs unprimed subjects

Statistical analysis description:

To assess the superiority of the haemagglutination inhibition (HI) antibody response against A/turkey/Turkey/01/2005 (H5N1) influenza strain 10 days following GSK1562902A formulation 2 vaccination at Day 182 in subjects previously primed with 2 doses of GSK1562902A vaccine (GSK1562902A formulation 1 Group) versus non primed subjects (GSK1562902A Formulation 2 - Havrix / Havrix Jr Group).

Comparison groups	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group v GSK1562902A Formulation 2 - Havrix / Havrix Jr Group
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority[2]
Parameter estimate	Adjusted GMT ratio
Point estimate	11.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.3
upper limit	19.2

Notes:

[2] - Criteria to be used for the objective:
If the lower limit of the 2-sided 95% confidence interval (CI) for the HI Geometric mean titre (GMT) ratio at Day 192 (GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group compared to GSK1562902A Formulation 2 - Havrix / Havrix Jr Group) was greater than 1.0, then the superiority of priming vaccination will have been shown and an anamnestic immune response demonstrated.

Primary: Number of subjects with any medically attended adverse events (MAEs)

End point title	Number of subjects with any medically attended adverse events (MAEs)[3]

End point description:

Any = occurrence of the symptom regardless of intensity grade. This outcome concerns solely subjects in the GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

End point type	Primary

End point timeframe:

From Day 0 to Day 182

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK1562902A Formulation 1 & 2 - Havrix/Havrix Jr pooled Group	GSK1562902A Formulation 2 - Havrix/Havrix Jr pooled Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	312	208		
Units: Subjects				
Any MAEs	115	64		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any medically attended adverse events (MAEs)

End point title	Number of subjects with any medically attended adverse events (MAEs)[4]

End point description:

Any = occurrence of the symptom regardless of intensity grade.

End point type	Primary

End point timeframe:

From Day 0 to Day 364.

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	156	156	104	104
Units: Subjects				
Any MAEs	65	84	41	41

Statistical analyses

No statistical analyses for this end point

Secondary: H5N1 HI antibody titres against the A/Indonesia/5/2005 and A/Turkey/Turkey/01/2005 (H5N1 virus) strains

End point title	H5N1 HI antibody titres against the A/Indonesia/5/2005 and A/Turkey/Turkey/01/2005 (H5N1 virus) strains

End point description:

The antibody titres were given as Geometric Mean Titer (GMT). A/Indonesia/5/2005 = A/INDO and A/Turkey/Turkey/01/2005 = A/TURK. For D192 , antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

For D364, antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

End point type	Secondary

End point timeframe:

At Days 0, 42, 182, 192, 364

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	152	103	101
Units: Titer				
geometric mean (confidence interval 95%)				
A/INDO, Day 0 [N=155,152,103,101]	5.7 (5.4 to 6)	5.5 (5.2 to 5.8)	5.4 (5.1 to 5.8)	5.8 (5.3 to 6.3)
A/INDO, Day 42 [N=155,152,103,101]	553.5 (490.9 to 624.1)	595 (522.1 to 678.2)	5.6 (5.2 to 6)	6.2 (5.6 to 7)
A/INDO, Day 182 [N=155,152,103,101]	52.2 (47.7 to 57.1)	54.1 (49.5 to 59.1)	5.1 (5 to 5.2)	5.6 (5.3 to 6)
A/INDO, Day 192 [N=127,NA,45,NA]	674.1 (595 to 763.8)	0 (0 to 0)	7.6 (6.7 to 8.5)	0 (0 to 0)
A/INDO, Day 364 [N=151,147,100,NA]	205.5 (183.3 to 230.4)	40.4 (36.8 to 44.5)	8.5 (7.6 to 9.4)	0 (0 to 0)
A/TURK, Day 0 [N=155,152,103,101]	7 (6.3 to 7.7)	6.4 (5.9 to 7)	6.1 (5.6 to 6.8)	7.2 (6.3 to 8.2)
A/TURK, Day 42 [N=155,152,103,101]	193 (172.1 to 216.5)	240.3 (188.1 to 240.3)	6.9 (6.9 to 7.9)	8.5 (7.2 to 10)
A/TURK, Day 182 [N=127,152,84,101]	39.6 (35.8 to 43.8)	42.5 (38.9 to 46.4)	6 (5.5 to 6.5)	7 (6.1 to 8)
A/TURK, Day 364 [N=151,147,100,NA]	215.1 (190.3 to 243.3)	35.4 (32.2 to 39)	18.4 (16.3 to 20.9)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: H5N1 HI neutralizing antibody titres against the A/Indonesia/5/2005 and A/turkey/Turkey/01/2005 (H5N1 virus) strains

End point title	H5N1 HI neutralizing antibody titres against the A/Indonesia/5/2005 and A/turkey/Turkey/01/2005 (H5N1 virus) strains

End point description:

Antibody titers were given as GMTs. A/Indonesia/5/2005 = A/INDO and A/Turkey/Turkey/01/2005 = A/TURK.
For D192 , antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.
For D364, antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

End point type	Secondary

End point timeframe:

At Days 0, 42, 182, 192, 364

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	151	147	100	102
Units: Titer				
geometric mean (confidence interval 95%)				
A/INDO, Day 0 [N=149,145,98,99]	16.6 (15.4 to 17.9)	16 (15 to 17)	15.3 (14.4 to 16.3)	16 (14.9 to 17.3)
A/INDO,Day 42 [N=150,146,99,100]	726.8 (646.1 to 817.6)	804.1 (710.8 to 909.5)	15.3 (14.4 to 16.4)	17 (15.1 to 19.1)
A/INDO, Day 182 [N=151,147,100,102]	133.3 (125.2 to 142)	140.7 (132.1 to 149.8)	15 (14.2 to 15.8)	14.7 (14 to 15.5)
A/INDO, Day 192 [N=149,NA,99,NA]	2128 (1864 to 2429.5)	0 (0 to 0)	38.6 (33.7 to 44.1)	0 (0 to 0)
A/INDO, Day 364 [N=149,147,100,NA]	523.1 (452.9 to 604.2)	132.7 (123.9 to 142.2)	30.4 (26.8 to 34.4)	0 (0 to 0)
A/TURK, Day 0, [N=149,145,98,100]	16.4 (15.3 to 17.6)	15.9 (15 to 16.9)	15.6 (14.5 to 16.8)	17.3 (15.8 to 19)
A/TURK, Day 42, [N=150,146,98,100]	155.7 (141.9 to 171)	162.7 (147.8 to 179.2)	16 (14.7 to 17.5)	17.6 (15.9 to 19.5)
A/TURK, Day 182, [N=151,147,100,101]	85.3 (79.7 to 91.2)	85.1 (79.2 to 91.3)	15.7 (14.6 to 16.8)	15.5 (14.5 to 16.5)
A/TURK, Day 192, [N=150,NA,100,NA]	1420.4 (1229.6 to 1640.8)	0 (0 to 0)	68.3 (58.2 to 80.2)	0 (0 to 0)
A/TURK, Day 364, [N=149,145,98,NA]	415.2 (359.2 to 479.9)	99.9 (92.6 to 107.9)	67.1 (59.6 to 75.5)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: 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.

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimeters (mm) of injection site. Relationship analysis was not performed.

End point type	Secondary

End point timeframe:

During a 7-day (Day 0-6) follow-up period after each vaccination

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	156	156	104	104
Units: Subjects				
Any Pain, D1 [N=156,156,104,104]	106	112	45	43
Grade 3 Pain, D1 [N=156,156,104,104]	2	3	1	1
Any Redness, D1 [N=156,156,104,104]	0	1	0	1
Grade 3 Redness, D1 [N=156,156,104,104]	0	0	0	0
Any Swelling, D1 [N=156,156,104,104]	9	9	0	1
Grade 3 Swelling, D1 [N=156,156,104,104]	0	0	0	0
Any Pain, D2 [N=156,156,104,103]	93	103	65	29
Grade 3 Pain, D2 [N=156,156,104,103]	3	0	0	0
Any Redness, D2 [N=156,156,104,103]	3	1	1	1
Grade 3 Redness, D2 [N=156,156,104,103]	0	0	0	0
Any Swelling, D2 [N=156,156,104,103]	7	7	2	1
Grade 3 Swelling, D2 [N=156,156,104,103]	0	0	0	0
Any Pain, D3 [N=156,154,0,0]	105	52	0	0
Grade 3 Pain, D3 [N=156,154,0,0]	0	0	0	0
Any Redness, D3 [N=156,154,0,0]	1	0	0	0
Grade 3 Redness, D3 [N=156,154,0,0]	0	0	0	0
Any Swelling, D3 [N=156,154,0,0]	4	0	0	0
Grade 3 Swelling, D3 [N=156,1540,0]	0	0	0	0
Any Pain, Across [N=156,156,104,104]	127	129	73	53
Grade 3 Pain, Across [N=156,156,104,104]	5	3	1	1
Any Redness, Across [N=156,156,104,104]	4	2	1	1
Grade 3 Redness, Across [N=156,156,104,104]	0	0	0	0
Any Swelling, Across [N=156,156,104,104]	15	13	2	1
Grade 3 Swelling, Across [N=156,156,104,104]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: 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.

End point description:

Assessed solicited general symptoms were diarrhea/vomiting, drowsiness, irritability/fussiness, loss of appetite and temperature [defined as axillary temperature equal to or above 38 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination. The symptoms were assessed for subjects aged less than 6 years.

End point type	Secondary

End point timeframe:

During a 7-day (Day 0-6) follow-up period after each vaccination

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	31	22	24
Units: Subjects				
Any diarrhoea/vomiting	2	3	2	0
Grade 3 diarrhoea/vomiting	0	0	0	0
Related diarrhoea/vomiting	2	3	2	0
Any drowsiness	5	8	3	2
Grade 3 drowsiness	0	2	0	0
Related drowsiness	5	8	3	2
Any irritability / fussiness	8	10	3	1
Grade 3 irritability / fussiness	0	0	0	0
Related irritability / fussiness	8	10	3	1
Any loss of appetite	8	9	3	1
Grade 3 loss of appetite	0	0	0	0
Related loss of appetite	8	8	3	1
Any temperature	12	11	1	0
Grade 3 temperature	2	4	1	0
Related temperature	11	10	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: 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.

End point description:

Assessed solicited general symptoms were arthralgia, fatigue, gastrointestinal symptoms, headache, myalgia and temperature[defined as axillary temperature equal to or above 38 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination. The symptoms were assessed for subjects aged 6 years or more.

End point type	Secondary

End point timeframe:
During a 7-day (Day 0-6) follow-up period after vaccination

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	125	82	80
Units: Subjects				
Any Arthralgia, D1	13	20	7	8
Grade 3 Arthralgia, D1	0	0	0	0
Related Arthralgia, D1	12	19	7	7
Any Fatigue,D1	16	16	8	8
Grade 3 Fatigue,D1	0	0	0	0
Related Fatigue,D1	15	16	8	7
Any Gastrointestinal symptoms, D1	9	5	6	7
Grade 3 Gastrointestinal symptoms, D1	0	0	0	1
Related Gastrointestinal symptoms, D1	7	5	6	6
Any Headache, D1	31	24	14	19
Grade 3 Headache, D1	1	1	0	0
Related Headache, D1	30	23	12	17
Any Myalgia, D1	14	23	8	11
Grade 3 Myalgia, D1	0	0	0	0
Related Myalgia, D1	14	22	8	10
Any Temperature/(Axillary), D1	10	2	6	7
Grade 3 Temperature/(Axillary), D1	1	1	2	1
Related Temperature/(Axillary), D1	8	1	3	5
Any Arthralgia, D2	11	18	5	3
Grade 3 Arthralgia, D2	0	0	0	0
Related Arthralgia, D2	11	18	5	3
Any Fatigue, D2	12	7	5	3
Grade 3 Fatigue, D2	0	0	0	0
Related Fatigue, D2	12	7	5	3
Any Gastrointestinal symptoms, D2	6	7	3	1
Grade 3 Gastrointestinal symptoms, D2	0	0	0	0
Related Gastrointestinal symptoms, D2	6	7	3	1
Any Headache, D2	40	37	8	12
Grade 3 Headache, D2	4	0	0	1
Related Headache, D2	39	37	8	12
Any Myalgia, D2	13	20	7	3
Grade 3 Myalgia, D2	0	0	0	0
Related Myalgia, D2	13	19	7	3
Any Temperature/(Axillary), D2	11	17	4	0
Grade 3 Temperature/(Axillary), D2	2	5	0	0
Related Temperature/(Axillary), D2	0	15	4	0
Any Arthralgia, D3	19	3	0	0
Grade 3 Arthralgia, D3	0	0	0	0
Related Arthralgia, D3	19	3	0	0

Any Fatigue, D3	15	8	0	0
Grade 3 Fatigue, D3	0	0	0	0
Related Fatigue, D3	15	8	0	0
Any Gastrointestinal symptoms, D3	4	6	0	0
Grade 3 Gastrointestinal symptoms, D3	0	0	0	0
Related Gastrointestinal symptoms, D3	4	6	0	0
Any Headache, D3	39	17	0	0
Grade 3 Headache, D3	1	0	0	0
Related Headache, D3	39	17	0	0
Any Myalgia, D3	15	2	0	0
Grade 3 Myalgia, D3	0	0	0	0
Related Myalgia, D3	15	2	0	0
Any Temperature/(Axillary), D3	7	2	0	0
Grade 3 Temperature/(Axillary), D3	0	0	0	0
Related Temperature/(Axillary), D3	7	2	0	0
Any Arthralgia, Across	33	31	11	11
Grade 3 Arthralgia, Across	0	0	0	0
Related Arthralgia, Across	32	30	11	10
Any Fatigue, Across	28	22	10	10
Grade 3 Fatigue, Across	0	0	0	0
Related Fatigue, Across	28	22	10	9
Any Gastrointestinal symptoms, Across	16	12	8	7
Grade 3 Gastrointestinal symptoms, Across	0	0	0	1
Related Gastrointestinal symptoms, Across	15	12	8	6
Any Headache, Across	63	52	20	24
Grade 3 Headache, Across	5	1	0	1
Related Headache, Across	62	51	18	22
Any Myalgia, Across	29	33	13	13
Grade 3 Myalgia, Across	0	0	0	0
Related Myalgia, Across	29	31	13	12
Any Temperature/(Axillary), Across	23	19	10	7
Grade 3 Temperature/(Axillary), Across	3	6	2	1
Related Temperature/(Axillary), Across	20	16	7	5

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

During a 21-day (Days 0 – 20) follow-up period after vaccination

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	156	156	104	104
Units: Subjects				
Any AEs	60	82	35	20
Grade 3 AEs	1	1	0	0
Related AEs	12	7	7	3

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

During Day 0 to Telephone Contact (TC) Day 84 overall.

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	156	156	104	104
Units: Subjects				
Any AEs	75	92	59	50
Grade 3 AEs	2	0	1	1
Related AEs	7	6	3	3

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any potential Immune-Mediated Diseases (pIMDs)

End point title	Number of subjects with any potential Immune-Mediated Diseases (pIMDs)

End point description:

End point type	Secondary

End point timeframe:

During the entire study period (Day 0 to 364)

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	156	156	104	104
Units: Subjects				
Any pIMDs	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs).

End point title	Number of subjects with serious adverse events (SAEs).

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

During the entire study period (Day 0 to 364)

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	156	156	104	104
Units: Subjects				
(SAEs).	4	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-H5N1 antibodies above the cut off values ≥1:10

End point title	Number of subjects with anti-H5N1 antibodies above the cut off values ≥1:10

End point description:

Seropositivity rates against the A/Indonesia/5/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group. Seropositivity rates against the A/turkey/Turkey/01/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 182, 192 and 364.

End point type	Secondary

End point timeframe:

At Days 0, 42, 182, 192 and 364

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	152	103	101
Units: Subjects				
A/INDO, Day 0 [N=155,152,103,101]	22	15	8	14
A/INDO, Day 42 [N=155,152,103,101]	155	151	9	19
A/INDO, Day 182 [N=155,152,103,101]	154	152	2	12
A/INDO, Day 192 [N=127,0,45,0]	127	0	37	0
A/INDO, Day 364 [N=151,147,100,0]	151	147	57	0
A/TURK, Day 182 [N=127,152,84,101]	126	152	17	26
A/TURK, Day 364 [N=151,147,100,0]	151	147	95	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroconverted subjects against the A/Indonesia/05/2005 strains of H5N1 influenza disease

End point title	Number of seroconverted subjects against the A/Indonesia/05/2005 strains of H5N1 influenza disease

End point description:

Seroconversion rates against the A/Indonesia/05/2005 (H5N1 VIRUS) strain were tabulated 95% CI on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group.

End point type	Secondary

End point timeframe:

At Days 42, 182, 192 and 364

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	152	103	101
Units: Subjects				
A/INDO, Day 42 [N=155,152,103,101]	154	151	1	1
A/INDO, Day 182 [N=155,152,103,101]	122	121	0	0
A/INDO, Day 192 [N=127,0,84,0]	127	0	3	0
A/INDO, Day 364 [N=151,147,100,0]	151	100	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against the A/Indonesia/05/2005 and A/turkey/Turkey/01/2005 strains of H5N1 influenza disease

End point title	Number of seroprotected subjects against the A/Indonesia/05/2005 and A/turkey/Turkey/01/2005 strains of H5N1 influenza disease

End point description:

Seroprotection rates against the A/Indonesia/5/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 -Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group. Seroprotection rates against the A/turkey/Turkey/01/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 182 and 192.

End point type	Secondary

End point timeframe:

At Days 0,42, 182, 192 and 364

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	152	103	101
Units: Subjects				
A/INDO, Day 0 [N=155,152,103,101]	0	0	2	1
A/INDO, Day 42 [N=155,152,103,101]	154	151	2	1
A/INDO, Day 182 [N=155,152,103,101]	125	122	0	0
A/INDO, Day 192 [N=127,0,84,0]	127	0	3	0
A/INDO, Day 364 [N=151,147,100,0]	151	102	1	0
A/TURK, Day 182 [N=127,0,84,0]	73	0	1	0
A/TURK, Day 192 [N=127,0,84,0]	127	0	28	0

Statistical analyses

No statistical analyses for this end point

Secondary: Mean geometric increase for anti-H5N1 antibody titers

End point title	Mean geometric increase for anti-H5N1 antibody titers

End point description:

MGI against the A/Indonesia/05/2005 (H5N1 VIRUS) strain were tabulated on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group. MGI against the A/turkey/Turkey/01/2005 (H5N1 virus) strain were tabulated on Days 42, 182 and 364.

End point type	Secondary

End point timeframe:

At Days 42, 182, 192 and 364

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	152	103	101
Units: Titer				
geometric mean (confidence interval 95%)				
A/INDO, Day 42 [N=155,152,103,101]	96.9 (84.9 to 110.4)	108.4 (94.2 to 124.7)	1 (1 to 1.1)	1.1 (0.9 to 1.2)
A/INDO, Day 182 [N=155,152,103,101]	9.1 (8.3 to 10.1)	9.8 (9 to 10.8)	0.9 (0.9 to 1)	1 (0.9 to 1.1)
A/INDO, Day 192 [N=127,0,84,0]	117.7 (103 to 134.5)	0 (0 to 0)	1.4 (1.2 to 1.6)	0 (0 to 0)
A/INDO, Day 364 [N=151,147,100,0]	36.2 (32 to 40.9)	7.4 (6.7 to 8.2)	1.6 (1.4 to 1.7)	0 (0 to 0)
A/TURK, Day 42 [N=155,152,103,101]	27.7 (24 to 31.9)	33.1 (28.6 to 38.3)	1.1 (1 to 1.3)	1.2 (1.1 to 1.3)

A/TURK, Day 182 [N=155,152,103,101]	5.6 (5 to 6.3)	6.6 (6 to 7.4)	1 (0.9 to 1.1)	1 (0.9 to 1.1)
A/TURK, Day 364 [N=151,147,100,0]	31.4 (26.9 to 36.7)	5.6 (5 to 6.3)	3 (2.6 to 3.4)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroconverted subjects against the A/turkey/Turkey/01/2005 strains of H5N1 influenza disease

End point title	Number of seroconverted subjects against the A/turkey/Turkey/01/2005 strains of H5N1 influenza disease[5]

End point description:

End point type	Secondary

End point timeframe:

At Days 192 and 364

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was made only on subjects receiving A/turkey/Turkey/01/2005 strain containing vaccine.

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	100		
Units: Subjects				
A/TURK, Day 192 [N=127,0,84,0]	127	27		
A/TURK, Day 364 [N=151,0,100,0]	105	18		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster factor for Hemagglutination Inhibition (HI) antibodies against the A/turkey/Turkey/01/2005 strain of H5N1 influenza disease

End point title	Booster factor for Hemagglutination Inhibition (HI) antibodies against the A/turkey/Turkey/01/2005 strain of H5N1 influenza disease[6]

End point description:

End point type	Secondary

End point timeframe:

At Days 192 and 364

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was made only on subjects receiving A/turkey/Turkey/01/2005 strain containing vaccine.

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	100		
Units: Titer				
geometric mean (confidence interval 95%)				
A/TURK, Day 192 [N=127,0,84,0]	18.6 (16.3 to 21.3)	4.1 (3.3 to 5.2)		
A/TURK, Day 364 [N=151,0,100,0]	5.6 (5 to 6.3)	3 (2.7 to 3.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with neutralizing anti-H5N1 antibody titers

End point title	Number of subjects with neutralizing anti-H5N1 antibody titers

End point description:

Seropositivity rates against the A/Indonesia/5/2005 (H5N1 virus) strain, were tabulated 95 % CI on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group. Seropositivity rates against the A/turkey/Turkey/01/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 0, 42,182, 192 and 364.

End point type	Secondary

End point timeframe:

At Days 0, 42, 182 192 and 364

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	151	147	100	102
Units: Subjects				
A/INDO, Day 0 [N=149,145,98,99]	22	17	8	14
A/INDO,Day 42 [N=150,146,99,100]	150	146	9	15
A/INDO, Day 182 [N=151,147,100,102]	150	147	7	4
A/INDO, Day 192 [N=149,0,99,0]	149	0	75	0
A/INDO, Day 364 [N=149,147,100,0]	149	147	73	0
A/TURK, Day 0, [N=149,145,98,100]	21	18	8	19

A/TURK, Day 42, [N=150,146,98,100]	150	145	10	20
A/TURK, Day 182, [N=151,147,100,101]	150	145	11	10
A/TURK, Day 192, [N=150,0,100,0]	150	0	90	0
A/TURK, Day 364, [N=149,145,98,0]	149	145	95	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with vaccine response rates (VRR) for H5N1 neutralizing antibodies

End point title	Number of subjects with vaccine response rates (VRR) for H5N1 neutralizing antibodies

End point description:

VRR was defined as the number of vaccinees who have at least a 4-fold increase in post-vaccination titre relative to pre-vaccination titre (Day 0).
For D192 , antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.
For D364, antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protoco

End point type	Secondary

End point timeframe:

At Days 42, 182 192 and 364

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group	Havrix / Havrix Jr Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	149	145	98	98
Units: Subjects				
A/INDO,Day 42 [N=149,144,98,98]	147	142	0	2
A/INDO, Day 182 [N=149,145,98,98]	127	115	0	0
A/INDO, Day 192 [N=147,0,97,0]	147	0	5	0
A/INDO, Day 364 [N=148,145,98,0]	144	126	8	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with booster vaccine response for H5N1 neutralizing antibodies

End point title	Number of subjects with booster vaccine response for H5N1 neutralizing antibodies[7]

End point description:

Booster VRR was defined as the number of vaccinees with at least a 4-fold increase in post-booster vaccination titre relative to pre-booster vaccination (Day 182).

End point type	Secondary

End point timeframe:

At Days 192 and 364

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was made only on subjects receiving A/turkey/Turkey/01/2005 strain containing vaccine.

End point values	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	150	100		
Units: Subjects				
A/TURK, Day 192, [N=150,0,100,0]	141	38		
A/TURK, Day 364, [N=149,0,98,0]	86	36		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Systematically-assessed symptoms: during the 7 days after each vaccination; unsolicited AEs: within 21 days after each vaccination and from Day 0 to Day 84. SAEs were collected throughout the study from Day 0 to Day 364.

Adverse event reporting additional description:

Solicited general symptoms were assessed in subjects aged less than 6 years and in subjects aged 6 years and more as required by the protocol.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group

Reporting group description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, a booster vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 dose of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Reporting group title	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group

Reporting group description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Reporting group title	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group

Reporting group description:

Subjects in this group received 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Reporting group title	Havrix / Havrix Jr Group

Reporting group description:

Subjects in this group received 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

Serious adverse events	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 156 (2.56%)	1 / 156 (0.64%)	0 / 104 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Open wound			
subjects affected / exposed	0 / 156 (0.00%)	1 / 156 (0.64%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 156 (0.64%)	0 / 156 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 156 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 156 (0.00%)	0 / 104 (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
Periorbital cellulitis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 156 (0.00%)	0 / 104 (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
Typhoid fever			
subjects affected / exposed	1 / 156 (0.64%)	0 / 156 (0.00%)	0 / 104 (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
Urinary tract infection			
subjects affected / exposed	1 / 156 (0.64%)	0 / 156 (0.00%)	0 / 104 (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

Serious adverse events	Havrix / Havrix Jr Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 104 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Open wound			

subjects affected / exposed	0 / 104 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 104 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 104 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 104 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital cellulitis			
subjects affected / exposed	0 / 104 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Typhoid fever			
subjects affected / exposed	0 / 104 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 104 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group	GSK1562902A Formulation 1 - Havrix / Havrix Jr Group	GSK1562902A Formulation 2 - Havrix / Havrix Jr Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	127 / 156 (81.41%)	129 / 156 (82.69%)	73 / 104 (70.19%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	127 / 156 (81.41%)	129 / 156 (82.69%)	73 / 104 (70.19%)
occurrences (all)	127	129	73
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	15 / 156 (9.62%)	13 / 156 (8.33%)	2 / 104 (1.92%)
occurrences (all)	15	13	2
Diarrhoea/vomiting			
alternative assessment type: Systematic			
subjects affected / exposed[1]	2 / 30 (6.67%)	3 / 31 (9.68%)	2 / 22 (9.09%)
occurrences (all)	2	3	3
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	5 / 30 (16.67%)	8 / 31 (25.81%)	3 / 22 (13.64%)
occurrences (all)	5	8	3
Irritability / fussiness			
alternative assessment type: Systematic			
subjects affected / exposed[3]	8 / 30 (26.67%)	10 / 31 (32.26%)	3 / 22 (13.64%)
occurrences (all)	8	10	3
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed[4]	8 / 30 (26.67%)	9 / 31 (29.03%)	3 / 22 (13.64%)
occurrences (all)	8	9	3
Temperature (subjects aged less than 6 years)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	12 / 30 (40.00%)	11 / 31 (35.48%)	1 / 22 (4.55%)
occurrences (all)	12	11	1
Arthralgia			

alternative assessment type: Systematic			
subjects affected / exposed[6]	33 / 126 (26.19%)	31 / 125 (24.80%)	11 / 82 (13.41%)
occurrences (all)	33	31	11
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed[7]	28 / 126 (22.22%)	22 / 125 (17.60%)	10 / 82 (12.20%)
occurrences (all)	28	22	10
Gastrointestinal symptoms			
alternative assessment type: Systematic			
subjects affected / exposed[8]	16 / 126 (12.70%)	12 / 125 (9.60%)	8 / 82 (9.76%)
occurrences (all)	16	12	8
Headache			
alternative assessment type: Systematic			
subjects affected / exposed[9]	63 / 126 (50.00%)	52 / 125 (41.60%)	20 / 82 (24.39%)
occurrences (all)	63	52	20
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed[10]	29 / 126 (23.02%)	33 / 125 (26.40%)	13 / 82 (15.85%)
occurrences (all)	29	33	13
Temperature (subjects aged 6 years or more)			
alternative assessment type: Systematic			
subjects affected / exposed[11]	23 / 126 (18.25%)	19 / 125 (15.20%)	10 / 82 (12.20%)
occurrences (all)	23	19	10
Infections and infestations			
Upper respiratory tract infection (within 21 days post-vaccination)			
subjects affected / exposed	31 / 156 (19.87%)	54 / 156 (34.62%)	9 / 104 (8.65%)
occurrences (all)	31	54	9
Viral infection (within 21 days post-vaccination)			
subjects affected / exposed	2 / 156 (1.28%)	10 / 156 (6.41%)	7 / 104 (6.73%)
occurrences (all)	2	10	7
Rhinitis			
subjects affected / exposed	5 / 156 (3.21%)	5 / 156 (3.21%)	6 / 104 (5.77%)
occurrences (all)	5	5	6
Upper respiratory tract infection			

(Day 0 up to Day 84 post-vaccination)			
subjects affected / exposed	45 / 156 (28.85%)	63 / 156 (40.38%)	31 / 104 (29.81%)
occurrences (all)	45	63	31
Nasopharyngitis			
subjects affected / exposed	3 / 156 (1.92%)	8 / 156 (5.13%)	3 / 104 (2.88%)
occurrences (all)	3	8	3
Viral infection (Day 0 up to Day 84 post-vaccination)			
subjects affected / exposed	10 / 156 (6.41%)	20 / 156 (12.82%)	18 / 104 (17.31%)
occurrences (all)	10	20	18

Non-serious adverse events	Havrix / Havrix Jr Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 104 (50.96%)		
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	53 / 104 (50.96%)		
occurrences (all)	53		
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 104 (0.96%)		
occurrences (all)	1		
Diarrhoea/vomiting			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 24 (0.00%)		
occurrences (all)	0		
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	2 / 24 (8.33%)		
occurrences (all)	2		
Irritability / fussiness			
alternative assessment type: Systematic			
subjects affected / exposed[3]	1 / 24 (4.17%)		
occurrences (all)	1		

Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed[4]	1 / 24 (4.17%)		
occurrences (all)	1		
Temperature (subjects aged less than 6 years)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 24 (0.00%)		
occurrences (all)	0		
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed[6]	11 / 80 (13.75%)		
occurrences (all)	11		
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed[7]	10 / 80 (12.50%)		
occurrences (all)	10		
Gastrointestinal symptoms			
alternative assessment type: Systematic			
subjects affected / exposed[8]	7 / 80 (8.75%)		
occurrences (all)	7		
Headache			
alternative assessment type: Systematic			
subjects affected / exposed[9]	24 / 80 (30.00%)		
occurrences (all)	24		
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed[10]	13 / 80 (16.25%)		
occurrences (all)	13		
Temperature (subjects aged 6 years or more)			
alternative assessment type: Systematic			
subjects affected / exposed[11]	7 / 80 (8.75%)		
occurrences (all)	7		
Infections and infestations			

Upper respiratory tract infection (within 21 days post-vaccination)			
subjects affected / exposed	9 / 104 (8.65%)		
occurrences (all)	9		
Viral infection (within 21 days post-vaccination)			
subjects affected / exposed	2 / 104 (1.92%)		
occurrences (all)	2		
Rhinitis			
subjects affected / exposed	2 / 104 (1.92%)		
occurrences (all)	2		
Upper respiratory tract infection (Day 0 up to Day 84 post-vaccination)			
subjects affected / exposed	27 / 104 (25.96%)		
occurrences (all)	27		
Nasopharyngitis			
subjects affected / exposed	6 / 104 (5.77%)		
occurrences (all)	6		
Viral infection (Day 0 up to Day 84 post-vaccination)			
subjects affected / exposed	10 / 104 (9.62%)		
occurrences (all)	10		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

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

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

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

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

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

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

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

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported