The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: 113866 (FLU D-PAN H1N1-AS03-033)

Title: Safety and immunogenicity study of GSK Biologicals' influenza vaccine GSK2340272A in adults aged 18 to 60 years.
GSK2340272A (Flu 1): GlaxoSmithKline (GSK) Biologicals' Pandemic influenza vaccine comprising A/California/7/2009 (H1N1)v-like strain adjuvanted with AS03.

Rationale: The aim of the study was to assess the safety and immunogenicity of Flu 1 vaccine as compared to GSK2340269A.
GSK2340269A (Flu 2): GSK Biologicals' Pandemic influenza vaccine comprising A/California/7/2009 (H1N1)v-like strain without adjuvant.

Phase: III

Study Period: 07 October 2009 to:

- 04 November 2009 (Day 21)
- 19 November 2009 (Day 42)
- 12 April 2010 (Day 182)
- 03 November 2010 (Day 364)

Study Design: Randomised (1:1), observer-blind study with 2 parallel groups.
Subjects were further stratified by age (18-40 years, 41-50 years and 51-60 years in the ratio 2:1:1)

Centres: 1 centre in Belgium.

Indication: Immunization against A/California/7/2009 (H1N1)v-like influenza in male and female subjects aged 18 to 60 years.

Treatment: Study groups were as follows:

- Flu 1 Group: subjects received 2 doses of Flu 1 vaccine.
- Flu 2 Group: subjects received 2 doses of Flu 2 vaccine.

Vaccines were given intramuscularly in the deltoid region of the non-dominant arm at Day 0 and of the dominant arm at Day 21.

Objectives:
To assess the haemagglutination-inhibition (HI) immune response to the vaccine homologous virus induced by vaccination with 2 doses of the Flu 1 or the Flu 2 vaccine in terms of European Medicines Agency (EMEA) (Committee for Medicinal Products for Human Use [CHMP]) guidance targets for pandemic vaccine seroconversion rate (SCR), seroprotection rate (SPR), and geometric mean fold rise (GMFR) at 21 days after the first dose of H1N1 vaccine in adults 18 to 60 years of age.

Primary Outcome/Efficacy Variable:
Humoral immune response in terms of vaccine HI antibodies in subjects from each vaccine group against A/California/7/2009 (H1N1)v-like virus
The following parameters were calculated with 95% confidence intervals (CIs):

- SCR* at 21 days after the first dose of study vaccine (Day 21)
- SPR** at 21 days after the first dose of H1N1 study vaccine (Day 21)
- GMFR*** at 21 days after the first dose of H1N1 study vaccine (Day 21).

*SCR was defined as the percentage of vaccinees that had either a pre-vaccination titre < 1:10 and a post-vaccination titre ≥ 1:40 or a pre-vaccination titre ≥ 1:10 and at least a four-fold increase in post-vaccination titre. The CHMP criterion was fulfilled if the point estimate for SCR was > 40% in subjects 18 to 60 years of age.
**SPR was defined as the percentage of vaccinees with a serum HI titre ≥ 1:40, that usually is accepted as indicating protection. The CHMP criterion was fulfilled if the post-vaccination time point estimate for SPR was > 70% in subjects 18 to 60 years of age.
***GMFR, also called seroconversion factor (SCF) was defined as the fold increase in serum HI geometric mean titres (GMTs) post-vaccination compared to pre-vaccination. The criterion was fulfilled if the point estimate for SCF was > 2.5 in subjects 18 to 60 years of age.

Secondary Outcome/Efficacy Variable(s):
Humoral immune response in terms of H1N1 HI antibodies in subjects from each vaccine group against A/California/7/2009 (H1N1)v-like virus,
The following parameters were calculated with 95% CIs:

- GMTs and seropositivity rates on Days 0, 21, 42, 182, and 364
- SCR* on Days 42, 182 and 364
- SPR* on Days 0, 42, 182 and 364

- SCF* on Days 42, 182 and 364

* Criteria for evaluation were the same as those presented in the primary outcome section
The same analyses as above were performed for each age stratum.

Humoral immune response in terms of neutralising antibodies against A/California/7/2009 (H1N1)v-like (in a subset of half of the subjects randomly selected)
The following parameters were calculated with 95% CIs: §

- GMTs of serum neutralising antibody titres on Days 0, 21, 42, 182 and 364
- SCRs* on Days 21, 42, 182 and 364.

§ Not available at the time of writing this summary.
*SCR was defined as the percentage of vaccinees that had a 4-fold increase between pre- and post-vaccination titres.

Safety:

- Occurrence, duration and intensity of each solicited local symptom within 7 days (Day 0 to Day 6) after each vaccination.
- Occurrence, duration, intensity and relation to vaccination of each solicited general symptom within 7 days (Day 0 to Day 6) after each vaccination.
- Occurrence, intensity and relationship to vaccination of unsolicited adverse events (AEs) within 21 days after the first vaccination (Day 0 to Day 20), and 63 days after the second vaccination (Day 21 to Day 83#), according to the Medical Dictionary for Regulatory Activities (MedDRA) classification.
- Occurrence and relationship to vaccination of AEs of specific interest (AESIs) / potential Immune-Mediated Disease (pIMDs) (AESIs/pIMDs for safety monitoring include autoimmune diseases and other immune-mediated inflammatory disorders) and serious adverse events (SAEs) during the entire study period (up to Day 364).

#Unsolicited AEs are presented for the period between Day 0 and Day 83.

Statistical Methods:
Analyses were performed on the Total Vaccinated cohort, the According-To-Protocol (ATP) cohort of immunogenicity, the ATP cohort for persistence at Month 6 and the ATP cohort for persistence at Month 12.

- The Total Vaccinated cohort included all vaccinated subjects.
- The ATP cohort of immunogenicity included all evaluable subjects (i.e., those meeting all eligibility criteria, complying with the procedures defined in the protocol, with no elimination criteria during the study), who received 2 vaccine doses and for whom assay results were available for antibodies against H1N1 antigen for the blood sample taken 21 days after each vaccine dose.
- The ATP cohort for persistence at Month 6/12 included all evaluable subjects (who met all eligibility criteria, complied with the procedures defined in the protocol during the study period and did not meet the elimination criteria), who had received at least one dose of study vaccine according to their treatment assignment, for whom data concerning immunogenicity outcome measures were available. This included subjects for whom assay results were available for antibodies against the study vaccine antigen component at Month 6/12.

Analysis of immunogenicity:
The analysis was done on the ATP cohort of immunogenicity and the ATP cohort for persistence at Month 6 and at Month 12.
Point estimate for SCR, SPR, SCF and the associated 95% CIs was computed on Day 21 after the first dose. If the point estimate for SCR is $\geq$ 40% and SPR $\geq$ 70%, the CHMP criteria for SCR and SPR are met, and if the SCF is > 2.5, the objectives are met.
The analysis of immunogenicity was done as a descriptive analysis of the humoral immune response in adults 18 to 60 years of age and for each age group. For the humoral immune response in terms of H1N1 HI antibodies (with 95% CIs), the following parameters were calculated:

- GMTs of H1N1 HI antibody titres at Day 0, 21, 42, 182 and 364
- SCR at Days 21, 42, 182 and 364
- SCF at Days 21, 42, 182 and 364
- SPR at Days 0, 21, 42, 182 and 364

Analysis of safety:
The analysis was based on the Total Vaccinated cohort.
The incidence of solicited local and general symptoms occurring during the 7 days after each vaccination was tabulated with exact 95% CI for each treatment group. The same calculations were performed for Grade 3 symptoms, as well as for solicited general symptoms assessed by the investigator as related to vaccination. All solicited local AEs were deemed causally related to vaccination.

The percentage of subjects with at least one report of an unsolicited AE classified by Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term during the 21-day follow-up period after the first vaccination (Day 0 to Day 20), and during the 84-day follow-up period after first vaccination (Day 0 to Day 83) were tabulated for each treatment group. The same tabulation was performed for grade 3 unsolicited AEs and for unsolicited AEs that were assessed by the investigator as possibly related to vaccination.
SAEs and AESIs/ pIMDs were collected and summarized through the entire follow-up period.

Study Population: Healthy male or female adults 18 to 60 years of age at the time of first vaccination. Women were to be of non-childbearing potential or if of childbearing potential, had to practice adequate contraception for 30 days prior to vaccination, to have a negative pregnancy test, and to continue such precautions during the entire treatment period and for 2 months after completion of the vaccination series. A written informed consent was obtained from the subjects prior to study entry.

Number of Subjects:	**Flu 1 Group**			**Flu 2 Group**		
	18-40Y	**41-50Y**	**51-60Y**	**18-40Y**	**41-50Y**	**51-60Y**
Planned, N	64			64		
Randomised, N (Total Vaccinated cohort)	32	16	17	33	17	16
Completed to Day 21, n (%)	32 (100)	16 (100)	17 (100)	33 (100)	17 (100)	16 (100)
Completed to Day 42, n (%)	32 (100)	16 (100)	17 (100)	33 (100)	17 (100)	16 (100)
Completed to Month 6 n (%)	32 (100)	16 (100)	17 (100)	32 (97.0)	17 (100)	16 (100)
Completed to Month 12, n (%)	32 (100)	16 (100)	16 (94.1)	32 (97.0)	17 (100)	16 (100)
Total Number Subjects Withdrawn, n (%)	0 (0.0)	0 (0.0)	1 (5.9)	1 (3.0)	0 (0.0)	0 (0.0)
Withdrawn due to Adverse Events n (%)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy n (%)	Not Applicable	Not Applicable	Not Applicable	Not applicable	Not Applicable	Not Applicable
Withdrawn for other reasons n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)
Demographics	**Flu 1 Group**			**Flu 2 Group**		
	18-40Y	**41-50Y**	**51-60Y**	**18-40Y**	**41-50Y**	**51-60Y**
N (Total Vaccinated cohort)	32	16	17	33	17	16
Females: Males	22:10	12:4	9:8	18:15	11:6	6:10
Mean Age, years (SD)	23.9 (4.75)	46.1 (2.31)	54.8 (2.63)	26.2 (5.45)	44.9 (2.69)	56.5 (2.97)
White-Caucasian/European heritage, n(%)	32 (100)	16 (100)	17 (100)	33 (100)	16 (94.1)	16 (100)

18-40Y = subjects aged 18 to 40 years
41-50Y = subjects aged 41 to 50 years
51-60Y = subjects aged 51 to 60 years

Primary Efficacy Results: Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) at Day 21 (Total Vaccinated cohort) - interim analysis posted at Day 21

					SCR			
							95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	36	32	88.9	73.9	96.9
		S+	PI(D21)	29	29	100	88.1	100
		Total	PI(D21)	65	61	93.8	85.0	98.3
	Flu 2	S-	PI(D21)	44	28	63.6	47.8	77.6
		S+	PI(D21)	20	17	85.0	62.1	96.8
		Total	PI(D21)	64	45	70.3	57.6	81.1

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n (%) = Number (percentage) of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= Day 21
Note: this interim analysis is superseded by the final analysis.

Primary Efficacy Results: Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged

between and including 18-60 years (ATP cohort of immunogenicity)

					SCR			
							95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	35	31	88.6	73.3	96.8
			PII(D42)	35	35	100	90.0	100
		S+	PI(D21)	29	29	100	88.1	100
			PII(D42)	29	29	100	88.1	100
		Total	PI(D21)*	64	60	93.8	84.8	98.3
			PII(D42)	64	64	100	94.4	100
	Flu 2	S-	PI(D21)	43	27	62.8	46.7	77.0
			PII(D42)	43	36	83.7	69.3	93.2
		S+	PI(D21)	20	17	85.0	62.1	96.8
			PII(D42)	20	18	90.0	68.3	98.8
		Total	PI(D21)*	63	44	69.8	57.0	80.8
			PII(D42)	63	54	85.7	74.6	93.3

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n (%) = Number (percentage) of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= post-dose 1, Day 21
PII(D42)=post-dose 2, Day 42
* Primary outcome variable

Primary Efficacy Results: Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09(H1N1) at Day 0 and Day 21 (Total Vaccinated cohort) - interim analysis posted at Day 21

					SPR			
							95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PRE	36	0	0.0	0.0	9.7
			PI(D21)*	36	32	88.9	73.9	96.9
		S+	PRE	29	7	24.1	10.3	43.5
			PI(D21)*	29	29	100	88.1	100
		Total	PRE	65	7	10.8	4.4	20.9
			PI(D21)*	65	61	93.8	85.0	98.3
	Flu 2	S-	PRE	44	0	0.0	0.0	8.0
			PI(D21)*	44	28	63.6	47.8	77.6
		S+	PRE	22	7	31.8	13.9	54.9
			PI(D21)*	20	19	95.0	75.1	99.9
		Total	PRE	66	7	10.6	4.4	20.6
			PI(D21)*	64	47	73.4	60.9	83.7

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with available results
n (%) = Number (percentage) of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE= Day 0
PI(D21)= Day 21
* Primary outcome variable
Note: this interim analysis is superseded by the final analysis.

Primary Efficacy Results: Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for all subjects aged between and including 18-60 years (ATP cohort of immunogenicity)

					SPR			
							95% CI	
Strain	**Group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PRE	35	0	0.0	0.0	10.0
			PI(D21)	35	31	88.6	73.3	96.8
			PII(D42)	35	35	100	90.0	100
		S+	PRE	29	7	24.1	10.3	43.5
			PI(D21)	29	29	100	88.1	100
			PII(D42)	29	29	100	88.1	100
		Total	PRE	64	7	10.9	4.5	21.2
			PI(D21)*	64	60	93.8	84.8	98.3
			PII(D42)	64	64	100	94.4	100
	Flu 2	S-	PRE	43	0	0.0	0.0	8.2
			PI(D21)	43	27	62.8	46.7	77.0
			PII(D42)	43	36	83.7	69.3	93.2
		S+	PRE	20	6	30.0	11.9	54.3
			PI(D21)	20	19	95.0	75.1	99.9
			PII(D42)	20	20	100	83.2	100
		Total	PRE	63	6	9.5	3.6	19.6
			PI(D21)*	63	46	73.0	60.3	83.4
			PII(D42)	63	56	88.9	78.4	95.4

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with available results
n (%) = Number (percentage) of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination, Day 0
PI(D21)= Post-dose 1, Day 21
PII(D42)= Post-dose 2, Day 42
* Primary outcome variable

Primary Efficacy Results: Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) at Day 21 (Total Vaccinated cohort) - interim analysis posted at Day 21

					GMFR		
						95% CI	
Vaccine strain	**Group**	**Sub-group**	**Timing**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	36	47.5	31.4	71.8
		S+	PI(D21)	29	41.3	28.6	59.8
		Total	PI(D21)	65	44.6	33.9	58.8
	Flu 2	S-	PI(D21)	44	12.0	7.7	18.8
		S+	PI(D21)	20	10.4	5.9	18.3
		Total	PI(D21)	64	11.5	8.1	16.3

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)=Day 21
Note: this interim analysis is superseded by the final analysis.

Primary Efficacy Results: Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 18-60 years (ATP cohort of immunogenicity)

					GMFR		
						95% CI	
Vaccine strain	**Group**	**Sub-group**	**Timing**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	35	47.1	30.8	72.0

			PII(D42)	35	105.0	80.4	137.1
		S+	PI(D21)	29	41.3	28.6	59.8
			PII(D42)	29	45.5	32.2	64.1
		Total	PI(D21)*	64	44.4	33.6	58.7
			PII(D42)	64	71.9	57.0	90.7
	Flu 2	S-	PI(D21)	43	12.0	7.6	18.9
			PII(D42)	43	21.4	14.8	30.9
		S+	PI(D21)	20	10.4	5.9	18.3
			PII(D42)	20	12.0	7.6	18.9
		Total	PI(D21)*	63	11.4	8.1	16.3
			PII(D42)	63	17.8	13.3	23.8

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= Post-dose 1, Day 21
PII(D42)= Post-dose 2, Day 42
* Primary outcome variable

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) by pre-vaccination status (Total Vaccinated cohort) – interim analysis posted at Day 21

					≥ 1:10				GMT		
							95% CI			95% CI	
Antibody	**Group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PRE	36	0	0.0	0.0	9.7	5.0	5.0	5.0
			PI(D21)	36	36	100	90.3	100	237.4	157.0	358.9
		S+	PRE	29	29	100	88.1	100	20.9	14.9	29.2
			PI(D21)	29	29	100	88.1	100	863.0	651.4	1143.2
		Total	PRE	65	29	44.6	32.3	57.5	9.5	7.5	11.9
			PI(D21)	65	65	100	94.5	100	422.2	312.5	570.3
	Flu 2	S-	PRE	44	0	0.0	0.0	8.0	5.0	5.0	5.0
			PI(D21)	44	39	88.6	75.4	96.2	60.2	38.5	94.2
		S+	PRE	22	22	100	84.6	100	26.1	17.5	38.8
			PI(D21)	20	20	100	83.2	100	269.4	136.7	530.9
		Total	PRE	66	22	33.3	22.2	46.0	8.7	6.9	10.9
			PI(D21)	64	59	92.2	82.7	97.4	96.2	64.3	143.9

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE =Day 0
PI(D21) = Day 21
Note: this interim analysis is superseded by the final analysis.

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) by pre-vaccination status for subjects in the age group 18-40 years (Total Vaccinated cohort) – interim analysis posted at Day 21

					≥ 1:10				GMT		
							95% CI			95% CI	
Antibody	**Group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PRE	15	0	0.0	0.0	21.8	5.0	5.0	5.0
			PI(D21)	15	15	100	78.2	100	452.7	281.3	728.5
		S+	PRE	17	17	100	80.5	100	27.6	16.1	47.3

			PI(D21)	17	17	100	80.5	100	1044.0	776.7	1403.4
		Total	PRE	32	17	53.1	34.7	70.9	12.4	8.2	18.7
			PI(D21)	32	32	100	89.1	100	705.7	523.8	950.7
	Flu 2	S-	PRE	18	0	0.0	0.0	18.5	5.0	5.0	5.0
			PI(D21)	18	17	94.4	72.7	99.9	98.8	49.8	196.0
		S+	PRE	15	15	100	78.2	100	31.7	18.7	53.7
			PI(D21)	13	13	100	75.3	100	365.8	146.6	913.0
		Total	PRE	33	15	45.5	28.1	63.6	11.6	7.8	17.3
			PI(D21)	31	30	96.8	83.3	99.9	171.1	96.7	302.8

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = Day 0
PI(D21) = Day 21
Note: this interim analysis is superseded by the final analysis.

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09. (H1N1) by pre-vaccination status for subjects in the age group 41-50 years (Total Vaccinated cohort) – interim analysis posted at Day 21

					≥ 1:10				**GMT**		
							95% CI			**95% CI**	
Antibody	**Group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PRE	12	0	0.0	0.0	26.5	5.0	5.0	5.0
			PI(D21)	12	12	100	73.5	100	213.5	113.8	400.3
		S+	PRE	4	4	100	39.8	100	12.9	7.6	21.9
			PI(D21)	4	4	100	39.8	100	698.1	224.0	2175.3
		Total	PRE	16	4	25.0	7.3	52.4	6.3	5.0	8.1
			PI(D21)	16	16	100	79.4	100	287.1	164.1	502.1
	Flu 2	S-	PRE	12	0	0.0	0.0	26.5	5.0	5.0	5.0
			PI(D21)	12	12	100	73.5	100	100.7	43.6	232.6
		S+	PRE	5	5	100	47.8	100	18.6	7.3	47.5
			PI(D21)	5	5	100	47.8	100	184.1	32.5	1043.8
		Total	PRE	17	5	29.4	10.3	56.0	7.4	5.1	10.7
			PI(D21)	17	17	100	80.5	100	120.2	60.7	238.0

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE= Day 0
PI(D21)= Day 21
Note: this interim analysis is superseded by the final analysis.

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) by pre-vaccination status for subjects in the age group 51-60 years (Total Vaccinated cohort) – interim analysis posted at Day 21

					≥ 1:10				**GMT**		
							95% CI			**95% CI**	
Antibody	**Group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PRE	9	0	0.0	0.0	33.6	5.0	5.0	5.0
			PI(D21)	9	9	100	66.4	100	93.2	30.5	284.7
		S+	PRE	8	8	100	63.1	100	14.6	11.5	18.6
			PI(D21)	8	8	100	63.1	100	640.1	278.0	1473.7

		Total	PRE	17	8	47.1	23.0	72.2	8.3	6.1	11.2
			PI(D21)	17	17	100	80.5	100	230.8	102.8	518.0
	Flu 2	S-	PRE	14	0	0.0	0.0	23.2	5.0	5.0	5.0
			PI(D21)	14	10	71.4	41.9	91.6	20.5	10.4	40.5
		S+	PRE	2	2	100	15.8	100	14.0	14.0	14.0
			PI(D21)	2	2	100	15.8	100	95.5	0.1	67258.1
		Total	PRE	16	2	12.5	1.6	38.3	5.7	4.7	6.9
			PI(D21)	16	12	75.0	47.6	92.7	24.8	12.9	47.9

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE= Day 0
PI(D21)= Day 21
Note: this interim analysis is superseded by the final analysis.

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) by pre-vaccination status for all subjects aged between and including 18-60 years (ATP cohort of immunogenicity)

					≥ 1:10				**GMT**		
							95% CI			**95% CI**	
Antibody	**Group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PRE	35	0	0.0	0.0	10.0	5.0	5.0	5.0
			PI(D21)	35	35	100	90.0	100	235.4	153.8	360.1
			PII(D42)	35	35	100	90.0	100	525.0	402.2	685.5
		S+	PRE	29	29	100	88.1	100	20.9	14.9	29.2
			PI(D21)	29	29	100	88.1	100	863.0	651.4	1143.2
			PII(D42)	29	29	100	88.1	100	949.4	748.2	1204.8
		Total	PRE	64	29	45.3	32.8	58.3	9.6	7.6	12.0
			PI(D21)	64	64	100	94.4	100	424.0	312.4	575.5
			PII(D42)	64	64	100	94.4	100	686.7	567.0	831.7
	Flu 2	S-	PRE	43	0	0.0	0.0	8.2	5.0	5.0	5.0
			PI(D21)	43	38	88.4	74.9	96.1	59.8	37.8	94.6
			PII(D42)	43	42	97.7	87.7	99.9	106.9	73.9	154.7
		S+	PRE	20	20	100	83.2	100	25.9	16.8	39.7
			PI(D21)	20	20	100	83.2	100	269.4	136.7	530.9
			PII(D42)	20	20	100	83.2	100	309.1	174.1	548.7
		Total	PRE	63	20	31.7	20.6	44.7	8.4	6.7	10.6
			PI(D21)	63	58	92.1	82.4	97.4	96.4	64.0	145.3
			PII(D42)	63	62	98.4	91.5	100	149.7	108.0	207.7

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE =Pre-vaccination, Day 0
PI(D21) = Post-dose 1, Day 21
PII(D42) = Post-dose 2, Day 42

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) by pre-vaccination status for the subjects aged between and including 18-40 years and 41-60 years (ATP cohort of immunogenicity)

						≥ 1:10				**GMT**		
								95% CI			**95% CI**	
Antibody	**Group**	**Sub-**	**Pre-**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**

		group	vacc status									
Flu A/CAL/7/09	Flu 1	18-40Y	S-	PRE	15	0	0.0	0.0	21.8	5.0	5.0	5.0
				PI(D21)	15	15	100	78.2	100	452.7	281.3	728.5
				PII(D42)	15	15	100	78.2	100	686.0	476.7	987.3
			S+	PRE	17	17	100	80.5	100	27.6	16.1	47.3
				PI(D21)	17	17	100	80.5	100	1044.0	776.7	1403.4
				PII(D42)	17	17	100	80.5	100	1132.6	874.0	1467.8
			Total	PRE	32	17	53.1	34.7	70.9	12.4	8.2	18.7
				PI(D21)	32	32	100	89.1	100	705.7	523.8	950.7
				PII(D42)	32	32	100	89.1	100	895.4	714.7	1121.8
		41-60Y	S-	PRE	20	0	0.0	0.0	16.8	5.0	5.0	5.0
				PI(D21)	20	20	100	83.2	100	144.1	79.6	260.9
				PII(D42)	20	20	100	83.2	100	429.6	293.7	628.6
			S+	PRE	12	12	100	73.5	100	14.0	11.7	16.9
				PI(D21)	12	12	100	73.5	100	658.9	376.7	1152.4
				PII(D42)	12	12	100	73.5	100	739.5	469.2	1165.3
			Total	PRE	32	12	37.5	21.1	56.3	7.4	6.1	8.9
				PI(D21)	32	32	100	89.1	100	254.8	156.7	414.4
				PII(D42)	32	32	100	89.1	100	526.7	393.1	705.6
	Flu 2	18-40Y	S-	PRE	18	0	0.0	0.0	18.5	5.0	5.0	5.0
				PI(D21)	18	17	94.4	72.7	99.9	98.8	49.8	196.0
				PII(D42)	18	18	100	81.5	100	131.8	75.3	230.6
			S+	PRE	13	13	100	75.3	100	32.2	17.7	58.5
				PI(D21)	13	13	100	75.3	100	365.8	146.6	913.0
				PII(D42)	13	13	100	75.3	100	429.1	205.8	894.6
			Total	PRE	31	13	41.9	24.5	60.9	10.9	7.2	16.5
				PI(D21)	31	30	96.8	83.3	99.9	171.1	96.7	302.8
				PII(D42)	31	31	100	88.8	100	216.2	134.8	346.8
		41-60Y	S-	PRE	25	0	0.0	0.0	13.7	5.0	5.0	5.0
				PI(D21)	25	21	84.0	63.9	95.5	41.7	22.5	77.0
				PII(D42)	25	24	96.0	79.6	99.9	91.9	54.8	154.2
			S+	PRE	7	7	100	59.0	100	17.2	9.6	30.8
				PI(D21)	7	7	100	59.0	100	152.6	49.3	472.5
				PII(D42)	7	7	100	59.0	100	168.1	62.7	450.9
			Total	PRE	32	7	21.9	9.3	40.0	6.5	5.3	8.1
				PI(D21)	32	28	87.5	71.0	96.5	55.4	32.0	95.7
				PII(D42)	32	31	96.9	83.8	99.9	104.9	67.4	163.2

18-40Y = Subjects aged between and including 18 years to 40 years
41-60Y = Subjects aged between and including 41 years to 60 years
S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE =Pre-vaccination, Day 0
PI(D21) = Post-dose 1, Day 21
PII(D42) = Post-dose 2, Day 42

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) by pre-vaccination status for the subjects aged between and including 41-50 years and 51-60 years (ATP cohort of immunogenicity)

						≥ 1:10				GMT		
								95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Pre-vacc**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**

			status									
Flu A/CAL/7/09	Flu 1	41-50Y	S-	PRE	12	0	0.0	0.0	26.5	5.0	5.0	5.0
				PI(D21)	12	12	100	73.5	100	213.5	113.8	400.3
				PII(D42)	12	12	100	73.5	100	427.2	297.6	613.3
			S+	PRE	4	4	100	39.8	100	12.9	7.6	21.9
				PI(D21)	4	4	100	39.8	100	698.1	224.0	2175.3
				PII(D42)	4	4	100	39.8	100	587.0	228.9	1505.2
			Total	PRE	16	4	25.0	7.3	52.4	6.3	5.0	8.1
				PI(D21)	16	16	100	79.4	100	287.1	164.1	502.1
				PII(D42)	16	16	100	79.4	100	462.5	340.9	627.5
		51-60Y	S-	PRE	8	0	0.0	0.0	36.9	5.0	5.0	5.0
				PI(D21)	8	8	100	63.1	100	79.9	23.4	273.5
				PII(D42)	8	8	100	63.1	100	433.4	168.0	1117.9
			S+	PRE	8	8	100	63.1	100	14.6	11.5	18.6
				PI(D21)	8	8	100	63.1	100	640.1	278.0	1473.7
				PII(D42)	8	8	100	63.1	100	829.9	432.1	1594.0
			Total	PRE	16	8	50.0	24.7	75.3	8.6	6.3	11.7
				PI(D21)	16	16	100	79.4	100	226.2	95.3	536.6
				PII(D42)	16	16	100	79.4	100	599.7	352.3	1020.8
	Flu 2	41-50Y	S-	PRE	11	0	0.0	0.0	28.5	5.0	5.0	5.0
				PI(D21)	11	11	100	71.5	100	102.8	40.7	259.9
				PII(D42)	11	11	100	71.5	100	160.1	76.1	336.6
			S+	PRE	5	5	100	47.8	100	18.6	7.3	47.5
				PI(D21)	5	5	100	47.8	100	184.1	32.5	1043.8
				PII(D42)	5	5	100	47.8	100	196.9	42.2	918.2
			Total	PRE	16	5	31.3	11.0	58.7	7.5	5.1	11.2
				PI(D21)	16	16	100	79.4	100	123.3	59.5	255.5
				PII(D42)	16	16	100	79.4	100	170.8	94.4	308.8
		51-60Y	S-	PRE	14	0	0.0	0.0	23.2	5.0	5.0	5.0
				PI(D21)	14	10	71.4	41.9	91.6	20.5	10.4	40.5
				PII(D42)	14	13	92.9	66.1	99.8	59.5	29.3	120.4
			S+	PRE	2	2	100	15.8	100	14.0	14.0	14.0
				PI(D21)	2	2	100	15.8	100	95.5	0.1	67258.1
				PII(D42)	2	2	100	15.8	100	113.1	1.4	9248.7
			Total	PRE	16	2	12.5	1.6	38.3	5.7	4.7	6.9
				PI(D21)	16	12	75.0	47.6	92.7	24.8	12.9	47.9
				PII(D42)	16	15	93.8	69.8	99.8	64.4	34.6	120.0

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE =Pre-vaccination, Day 0
PI(D21) = Post-dose 1, Day 21
PII(D42) = Post-dose 2, Day 42

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) for all subjects aged between and including 18-60 years (ATP cohort for persistence at Month 6)

				≥ 1:10				**GMT**		
						95% CI			**95% CI**	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D182)	64	64	100	94.4	100	222.6	172.4	287.4
	Flu2	PII(D182)	63	59	93.7	84.5	98.2	80.4	55.1	117.2

GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(D182) = Post-dose 2, Day 182

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) for all subjects aged between and including 18-40 years (ATP cohort for persistence at Month 6)

				≥1:10				GMT		
						95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D182)	32	32	100	89.1	100	269.1	183.9	393.9
	Flu2	PII(D182)	31	29	93.5	78.6	99.2	132.3	75.9	230.4

GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(D182) = Post-dose 2, Day 182

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) for all subjects aged between and including 41-50 and 51-60 years (ATP cohort for persistence at Month 6)

					≥1:10				GMT		
							95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	41-50Y	PII(D182)	16	16	100	79.4	100	182.2	126.8	261.7
		51-60Y	PII(D182)	16	16	100	79.4	100	186.1	97.5	355.4
	Flu2	41-50Y	PII(D182)	16	16	100	79.4	100	99.3	47.8	206.6
		51-60Y	PII(D182)	16	14	87.5	61.7	98.4	24.8	15.6	39.6

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(D182) = Post-dose 2, Day 182

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) for all subjects aged between and including 18-60 years (ATP cohort for persistence at Month 12)

				≥ 1:10				GMT		
						95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D364)	61	60	98.4	91.2	100	76.8	58.1	101.5
	Flu2	PII(D364)	61	49	80.3	68.2	89.4	35.2	24.0	51.7

GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) for all subjects aged between and including 18-40 years (ATP cohort for persistence at Month 12)

				≥ 1:10				GMT		
						95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D364)	30	30	100	88.4	100	96.2	63.1	146.7
	Flu2	PII(D364)	29	26	89.7	72.6	97.8	57.2	32.2	101.8

GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09 (H1N1) for all subjects aged between and including 41-50 and 51-60 years (ATP cohort for persistence at Month 12)

					≥ 1:10				GMT		
							95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	41-50Y	PII(D364)	16	16	100	79.4	100	57.7	38.4	86.8
		51-60Y	PII(D364)	15	14	93.3	68.1	99.8	66.4	33.1	133.2
	Flu2	41-50Y	PII(D364)	16	14	87.5	61.7	98.4	48.4	23.2	101.1
		51-60Y	PII(D364)	16	9	56.3	29.9	80.2	10.6	6.8	16.7

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
GMT = geometric mean antibody titre calculated on all subjects
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with titre within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 18-40 years (ATP cohort of immunogenicity)

					SCR			
							95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	15	15	100	78.2	100
			PII(D42)	15	15	100	78.2	100
		S+	PI(D21)	17	17	100	80.5	100
			PII(D42)	17	17	100	80.5	100
		Total	PI(D21)	32	32	100	89.1	100
			PII(D42)	32	32	100	89.1	100
	Flu 2	S-	PI(D21)	18	14	77.8	52.4	93.6
			PII(D42)	18	15	83.3	58.6	96.4
		S+	PI(D21)	13	11	84.6	54.6	98.1
			PII(D42)	13	12	92.3	64.0	99.8
		Total	PI(D21)	31	25	80.6	62.5	92.5
			PII(D42)	31	27	87.1	70.2	96.4

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= post-dose 1, Day 21
PII(D42)= post-dose 2, Day 42

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 41-50 years (ATP cohort of immunogenicity)

					SCR			
							95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	12	12	100	73.5	100
			PII(D42)	12	12	100	73.5	100
		S+	PI(D21)	4	4	100	39.8	100
			PII(D42)	4	4	100	39.8	100

		Total	PI(D21)	16	16	100	79.4	100
			PII(D42)	16	16	100	79.4	100
	Flu 2	S-	PI(D21)	11	8	72.7	39.0	94.0
			PII(D42)	11	11	100	71.5	100
		S+	PI(D21)	5	4	80.0	28.4	99.5
			PII(D42)	5	4	80.0	28.4	99.5
		Total	PI(D21)	16	12	75.0	47.6	92.7
			PII(D42)	16	15	93.8	69.8	99.8

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= post-dose 1, Day 21
PII(D42)= post-dose 2, Day 42

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 51-60 years (ATP cohort of immunogenicity)

					SCR			
							95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	8	4	50.0	15.7	84.3
			PII(D42)	8	8	100	63.1	100
		S+	PI(D21)	8	8	100	63.1	100
			PII(D42)	8	8	100	63.1	100
		Total	PI(D21)	16	12	75.0	47.6	92.7
			PII(D42)	16	16	100	79.4	100
	Flu 2	S-	PI(D21)	14	5	35.7	12.8	64.9
			PII(D42)	14	10	71.4	41.9	91.6
		S+	PI(D21)	2	2	100	15.8	100
			PII(D42)	2	2	100	15.8	100
		Total	PI(D21)	16	7	43.8	19.8	70.1
			PII(D42)	16	12	75.0	47.6	92.7

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= post-dose 1, Day 21
PII(D42)= post-dose 2, Day 42

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 18-60 years at Day 182 (ATP cohort for persistence at Month 6)

			SCR			
					95% CI	
Strain	**Group**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	64	60	93.8	84.8	98.3
	Flu2	63	42	66.7	53.7	78.0

Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre

N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 18-40 years at Day 182 (ATP cohort for persistence at Month 6)

			SCR			
					95% CI	
Strain	**Group**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	32	30	93.8	79.2	99.2
	Flu2	31	25	80.6	62.5	92.5

Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 41-50 and 51-60 years at Day 182 (ATP cohort for persistence at Month 6)

				SCR			
						95% CI	
Strain	**Group**	**Sub-group**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	41-50Y	16	16	100	79.4	100
		51-60Y	16	14	87.5	61.7	98.4
	Flu2	41-50Y	16	11	68.8	41.3	89.0
		51-60Y	16	6	37.5	15.2	64.6

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 18-60 years (ATP cohort for persistence at Month 12)

				SCR			
						95% CI	
Strain	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D364)	61	44	72.1	59.2	82.9
	Flu2	PII(D364)	61	22	36.1	24.2	49.4

Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 18-40 years (ATP cohort for persistence at Month 12)

				SCR			
						95% CI	
Strain	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D364)	30	23	76.7	57.7	90.1
	Flu2	PII(D364)	29	14	48.3	29.4	67.5

Seroconversion defined as:

For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Seroconversion rate (SCR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for subjects aged between and including 41-50 and 51-60 years (ATP cohort for persistence at Month 12)

					SCR			
							95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	41-50Y	PII(D364)	16	11	68.8	41.3	89.0
		51-60Y	PII(D364)	15	10	66.7	38.4	88.2
	Flu2	41-50Y	PII(D364)	16	6	37.5	15.2	64.6
		51-60Y	PII(D364)	16	2	12.5	1.6	38.3

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for the subjects aged between and including 18-40 years and 41-60 years (ATP cohort of immunogenicity)

						SPR			
								95% CI	
Strain	**Group**	**Sub-group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	18-40Y	S-	PRE	15	0	0.0	0.0	21.8
				PI(D21)	15	15	100	78.2	100
				PII(D42)	15	15	100	78.2	100
			S+	PRE	17	7	41.2	18.4	67.1
				PI(D21)	17	17	100	80.5	100
				PII(D42)	17	17	100	80.5	100
			Total	PRE	32	7	21.9	9.3	40.0
				PI(D21)	32	32	100	89.1	100
				PII(D42)	32	32	100	89.1	100
		41-60Y	S-	PRE	20	0	0.0	0.0	16.8
				PI(D21)	20	16	80.0	56.3	94.3
				PII(D42)	20	20	100	83.2	100
			S+	PRE	12	0	0.0	0.0	26.5
				PI(D21)	12	12	100	73.5	100
				PII(D42)	12	12	100	73.5	100
			Total	PRE	32	0	0.0	0.0	10.9
				PI(D21)	32	28	87.5	71.0	96.5
				PII(D42)	32	32	100	89.1	100
	Flu 2	18-40Y	S-	PRE	18	0	0.0	0.0	18.5
				PI(D21)	18	14	77.8	52.4	93.6
				PII(D42)	18	15	83.3	58.6	96.4
			S+	PRE	13	5	38.5	13.9	68.4
				PI(D21)	13	12	92.3	64.0	99.8
				PII(D42)	13	13	100	75.3	100
			Total	PRE	31	5	16.1	5.5	33.7

				PI(D21)	31	26	83.9	66.3	94.5
				PII(D42)	31	28	90.3	74.2	98.0
		41-60Y	S-	PRE	25	0	0.0	0.0	13.7
				PI(D21)	25	13	52.0	31.3	72.2
				PII(D42)	25	21	84.0	63.9	95.5
			S+	PRE	7	1	14.3	0.4	57.9
				PI(D21)	7	7	100	59.0	100
				PII(D42)	7	7	100	59.0	100
			Total	PRE	32	1	3.1	0.1	16.2
				PI(D21)	32	20	62.5	43.7	78.9
				PII(D42)	32	28	87.5	71.0	96.5

18-40Y = Subjects aged between and including 18 years to 40 years
41-60Y = Subjects aged between and including 41 years to 60 years
S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination, Day 0
PI(D21)= Post-dose 1, Day 21
PII(D42)= Post-dose 2, Day 42

Secondary Outcome Variable(s): Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for the subjects aged between and including 41-50 years and 51-60 years (ATP cohort of immunogenicity)

						SPR			
								95% CI	
Strain	**Group**	**Sub-group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	41-50Y	S-	PRE	12	0	0.0	0.0	26.5
				PI(D21)	12	12	100	73.5	100
				PII(D42)	12	12	100	73.5	100
			S+	PRE	4	0	0.0	0.0	60.2
				PI(D21)	4	4	100	39.8	100
				PII(D42)	4	4	100	39.8	100
			Total	PRE	16	0	0.0	0.0	20.6
				PI(D21)	16	16	100	79.4	100
				PII(D42)	16	16	100	79.4	100
		51-60Y	S-	PRE	8	0	0.0	0.0	36.9
				PI(D21)	8	4	50.0	15.7	84.3
				PII(D42)	8	8	100	63.1	100
			S+	PRE	8	0	0.0	0.0	36.9
				PI(D21)	8	8	100	63.1	100
				PII(D42)	8	8	100	63.1	100
			Total	PRE	16	0	0.0	0.0	20.6
				PI(D21)	16	12	75.0	47.6	92.7
				PII(D42)	16	16	100	79.4	100
	Flu 2	41-50Y	S-	PRE	11	0	0.0	0.0	28.5
				PI(D21)	11	8	72.7	39.0	94.0
				PII(D42)	11	11	100	71.5	100
			S+	PRE	5	1	20.0	0.5	71.6
				PI(D21)	5	5	100	47.8	100
				PII(D42)	5	5	100	47.8	100
			Total	PRE	16	1	6.3	0.2	30.2
				PI(D21)	16	13	81.3	54.4	96.0
				PII(D42)	16	16	100	79.4	100
		51-60Y	S-	PRE	14	0	0.0	0.0	23.2

				PI(D21)	14	5	35.7	12.8	64.9
				PII(D42)	14	10	71.4	41.9	91.6
			S+	PRE	2	0	0.0	0.0	84.2
				PI(D21)	2	2	100	15.8	100
				PII(D42)	2	2	100	15.8	100
			Total	PRE	16	0	0.0	0.0	20.6
				PI(D21)	16	7	43.8	19.8	70.1
				PII(D42)	16	12	75.0	47.6	92.7

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination, Day 0
PI(D21)= Post-dose 1, Day 21
PII(D42)= Post-dose 2, Day 42

Secondary Outcome Variable(s): Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for the subjects aged between and including 18-60 years at Day 182 (ATP cohort for persistence Month 6)

				SPR		
					95% CI	
Strain	**Group**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	64	62	96.9	89.2	99.6
	Flu2	63	45	71.4	58.7	82.1

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for the subjects aged between and including 18-40 years at Day 182 (ATP cohort for persistence Month 6)

			SPR			
					95% CI	
Strain	**Group**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	32	32	100	89.1	100
	Flu2	31	26	83.9	66.3	94.5

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for the subjects aged between and including 41-50 and 51-60 years at Day 182 (ATP cohort for persistence Month 6)

				SPR			
						95% CI	
Strain	**Group**	**Sub-group**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	41-50Y	16	16	100	79.4	100
		51-60Y	16	14	87.5	61.7	98.4
	Flu2	41-50Y	16	12	75.0	47.6	92.7
		51-60Y	16	7	43.8	19.8	70.1

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for the subjects aged between and including 18-60 years (ATP cohort for persistence Month 12)

	SPR

						95% CI	
Strain	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D364)	61	48	78.7	66.3	88.1
	Flu2	PII(D364)	61	26	42.6	30.0	55.9

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for the subjects aged between and including 18-40 years (ATP cohort for persistence Month 12)

				SPR			
						95% CI	
Strain	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D364)	30	26	86.7	69.3	96.2
	Flu2	PII(D364)	29	17	58.6	38.9	76.5

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Seroprotection rates (SPR) for HI antibodies against Flu A/CAL/7/09 (H1N1) for the subjects aged between and including 41-50 and 51-60 years (ATP cohort for persistence Month 12)

					SPR			
							95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	41-50Y	PII(D364)	16	11	68.8	41.3	89.0
		51-60Y	PII(D364)	15	11	73.3	44.9	92.2
	Flu2	41-50Y	PII(D364)	16	7	43.8	19.8	70.1
		51-60Y	PII(D364)	16	2	12.5	1.6	38.3

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 18-40 years (ATP cohort of immunogenicity)

				GMFR		
					95% CI	
Vaccine strain	**Group**	**Timing**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	PI(D21)	15	90.5	56.3	145.7
		PII(D42)	15	137.2	95.3	197.5
		PI(D21)	17	37.8	21.8	65.5
		PII(D42)	17	41.0	24.0	70.0
		PI(D21)	32	56.9	38.9	83.4
		PII(D42)	32	72.2	49.3	105.9
	Flu 2	PI(D21)	18	19.8	10.0	39.2
		PII(D42)	18	26.4	15.1	46.1
		PI(D21)	13	11.3	5.3	24.5
		PII(D42)	13	13.3	7.3	24.3
		PI(D21)	31	15.7	9.6	25.6
		PII(D42)	31	19.8	13.2	29.7

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])

95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= Post-dose 1, Day 21
PII(D42)= Post-dose 2, Day 42

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 41-50 years (ATP cohort of immunogenicity)

					GMFR		
						95% CI	
Vaccine strain	**Group**	**Sub-group**	**Timing**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	12	42.7	22.8	80.1
			PII(D42)	12	85.4	59.5	122.7
		S+	PI(D21)	4	54.0	17.2	169.0
			PII(D42)	4	45.4	21.0	98.2
		Total	PI(D21)	16	45.3	27.8	73.6
			PII(D42)	16	72.9	52.9	100.6
	Flu 2	S-	PI(D21)	11	20.6	8.1	52.0
			PII(D42)	11	32.0	15.2	67.3
		S+	PI(D21)	5	9.9	1.9	51.7
			PII(D42)	5	10.6	2.5	44.7
		Total	PI(D21)	16	16.4	7.9	33.9
			PII(D42)	16	22.7	11.9	43.1

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= Post-dose 1, Day 21
PII(D42)= Post-dose 2, Day 42

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 51-60 years (ATP cohort of immunogenicity)

					GMFR		
						95% CI	
Vaccine strain	**Group**	**Sub-group**	**Timing**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu 1	S-	PI(D21)	8	16.0	4.7	54.7
			PII(D42)	8	86.7	33.6	223.6
		S+	PI(D21)	8	43.7	20.0	95.7
			PII(D42)	8	56.7	29.4	109.4
		Total	PI(D21)	16	26.4	13.2	52.9
			PII(D42)	16	70.1	41.9	117.4
	Flu 2	S-	PI(D21)	14	4.1	2.1	8.1
			PII(D42)	14	11.9	5.9	24.1
		S+	PI(D21)	2	6.8	0.0	4804.2
			PII(D42)	2	8.1	0.1	660.6
		Total	PI(D21)	16	4.4	2.4	8.0
			PII(D42)	16	11.3	6.1	20.9

S- = seronegative subjects (antibody titre < 1:10) prior to vaccination
S+ = seropositive subjects (antibody titre ≥ 1:10) prior to vaccination
N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21)= Post-dose 1, Day 21
PII(D42)= Post-dose 2, Day 42

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 18-60 years at Day 182 (ATP cohort for persistence at Month 6)

	GMFR	
		95% CI

Strain	Group	N	Value	LL	UL
Flu A/CAL/7/09	Flu1	64	23.3	18.5	29.3
	Flu2	63	9.5	7.0	13.1

N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 18-40 years at Day 182 (ATP cohort for persistence at Month 6)

			GMFR		
				95% CI	
Strain	**Group**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	32	21.7	15.4	30.6
	Flu2	31	12.1	7.7	19.0

N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 41-50 and 51-60 years at Day 182 (ATP cohort for persistence at Month 6)

				GMFR		
					95% CI	
Strain	**Group**	**Sub-group**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	41-50Y	16	28.7	19.1	43.2
		51-60Y	16	21.8	12.7	37.2
	Flu2	41-50Y	16	13.2	6.3	27.6
		51-60Y	16	4.4	2.8	6.8

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 18-60 years (ATP cohort for persistence at Month 12)

				GMFR		
					95% CI	
Strain	**Group**	**Timing**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D364)	61	8.5	6.5	11.0
	Flu2	PII(D364)	61	4.4	3.1	6.0

N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 18-40 years (ATP cohort for persistence at Month 12)

				GMFR		
					95% CI	
Strain	**Group**	**Timing**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	PII(D364)	30	8.4	5.5	12.8
	Flu2	PII(D364)	29	5.6	3.5	8.9

N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Geometric mean fold rise (GMFR) for HI antibody titre against Flu A/CAL/7/09 (H1N1) for subjects in the age group 41-50 and 51-60 years (ATP cohort for persistence at Month 12)

	GMFR

						95% CI	
Strain	**Group**	**Sub-group**	**Timing**	**N**	**Value**	**LL**	**UL**
Flu A/CAL/7/09	Flu1	41-50Y	PII(D364)	16	9.1	5.7	14.5
		51-60Y	PII(D364)	15	8.0	4.7	13.8
	Flu2	41-50Y	PII(D364)	16	6.4	3.1	13.4
		51-60Y	PII(D364)	16	1.9	1.2	2.9

41-50Y = Subjects aged between and including 41 years to 50 years
51-60Y = Subjects aged between and including 51 years to 60 years
N = Number of subjects with pre- and post-vaccination results available
GMFR = geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D364)= Post-dose 2, Day 364

Secondary Outcome Variable(s): Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total Vaccinated cohort)

		Flu 1 Group					Flu 2 Group				
					95 % CI					95 % CI	
Symptom	**Intensity**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 1											
Pain	Any	65	60	92.3	83.0	97.5	66	16	24.2	14.5	36.4
	Grade 3	65	1	1.5	0.0	8.3	66	0	0.0	0.0	5.4
Redness	Any	65	4	6.2	1.7	15.0	66	0	0.0	0.0	5.4
	> 100 mm	65	0	0.0	0.0	5.5	66	0	0.0	0.0	5.4
Swelling	Any	65	8	12.3	5.5	22.8	66	0	0.0	0.0	5.4
	> 100 mm	65	0	0.0	0.0	5.5	66	0	0.0	0.0	5.4
Dose 2											
Pain	Any	64	57	89.1	78.8	95.5	64	11	17.2	8.9	28.7
	Grade 3	64	1	1.6	0.0	8.4	64	0	0.0	0.0	5.6
Redness	Any	64	6	9.4	3.5	19.3	64	0	0.0	0.0	5.6
	> 100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6
Swelling	Any	64	6	9.4	3.5	19.3	64	0	0.0	0.0	5.6
	> 100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6
Across doses											
Pain	Any	65	62	95.4	87.1	99.0	66	21	31.8	20.9	44.4
	Grade 3	65	1	1.5	0.0	8.3	66	0	0.0	0.0	5.4
Redness	Any	65	9	13.8	6.5	24.7	66	0	0.0	0.0	5.4
	> 100 mm	65	0	0.0	0.0	5.5	66	0	0.0	0.0	5.4
Swelling	Any	65	11	16.9	8.8	28.3	66	0	0.0	0.0	5.4
	> 100 mm	65	0	0.0	0.0	5.5	66	0	0.0	0.0	5.4

N= number of subjects with at least one documented dose
n/%= number/percentage of subjects reporting at least once the symptom
95% confidence interval; LL = lower limit, UL = upper limit
Any= occurrence of any local symptom regardless of intensity grade
Grade 3 pain= significant pain at rest that prevented normal activities

Secondary Outcome Variable(s): Number of days with any local symptoms during the solicited post-vaccination period (Total Vaccinated cohort)

Solicited symptom	**Dose**	**Group**	**N**	**Mean**	**Median**
Pain	Dose 1	Flu 1	60	3.4	3.0
		Flu 2	16	1.8	2.0
	Dose 2	Flu 1	57	3.2	3.0
		Flu 2	11	1.7	2.0
	Across doses	Flu 1	117	3.3	3.0
		Flu 2	27	1.7	2.0
Redness	Dose 1	Flu 1	4	2.0	2.0
	Dose 2	Flu 1	6	3.0	2.5
	Across doses	Flu 1	10	2.6	2.0

Swelling	Dose 1	Flu 1	8	1.9	1.5
	Dose 2	Flu 1	6	2.3	2.0
	Across doses	Flu 1	14	2.1	2.0

N = number of doses with the symptom

Secondary Outcome Variable(s): Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total Vaccinated cohort)

		Flu 1 Group					Flu 2 Group				
					95 % CI					95 % CI	
Symptom	**Intensity/ Relationship**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 1											
Fatigue	Any	65	31	47.7	35.1	60.5	66	22	33.3	22.2	46.0
	Grade 3	65	0	0.0	0.0	5.5	66	2	3.0	0.4	10.5
	Related	65	28	43.1	30.8	56.0	66	18	27.3	17.0	39.6
Headache	Any	65	25	38.5	26.7	51.4	66	16	24.2	14.5	36.4
	Grade 3	65	1	1.5	0.0	8.3	66	0	0.0	0.0	5.4
	Related	65	22	33.8	22.6	46.6	66	11	16.7	8.6	27.9
Joint pain at other location	Any	65	13	20.0	11.1	31.8	66	4	6.1	1.7	14.8
	Grade 3	65	1	1.5	0.0	8.3	66	1	1.5	0.0	8.2
	Related	65	12	18.5	9.9	30.0	66	2	3.0	0.4	10.5
Muscle aches	Any	65	17	26.2	16.0	38.5	66	6	9.1	3.4	18.7
	Grade 3	65	1	1.5	0.0	8.3	66	1	1.5	0.0	8.2
	Related	65	16	24.6	14.8	36.9	66	5	7.6	2.5	16.8
Shivering	Any	65	9	13.8	6.5	24.7	66	6	9.1	3.4	18.7
	Grade 3	65	0	0.0	0.0	5.5	66	1	1.5	0.0	8.2
	Related	65	9	13.8	6.5	24.7	66	6	9.1	3.4	18.7
Sweating	Any	65	9	13.8	6.5	24.7	66	9	13.6	6.4	24.3
	Grade 3	65	0	0.0	0.0	5.5	66	1	1.5	0.0	8.2
	Related	65	8	12.3	5.5	22.8	66	9	13.6	6.4	24.3
Temperature/(Axillary)	≥37.5°C	65	2	3.1	0.4	10.7	66	2	3.0	0.4	10.5
	≥39°C	65	0	0.0	0.0	5.5	66	0	0.0	0.0	5.4
	Related	65	1	1.5	0.0	8.3	66	2	3.0	0.4	10.5
Dose 2											
Fatigue	Any	64	28	43.8	31.4	56.7	64	15	23.4	13.8	35.7
	Grade 3	64	2	3.1	0.4	10.8	64	0	0.0	0.0	5.6
	Related	64	27	42.2	29.9	55.2	64	13	20.3	11.3	32.2
Headache	Any	64	21	32.8	21.6	45.7	64	10	15.6	7.8	26.9
	Grade 3	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6
	Related	64	20	31.3	20.2	44.1	64	9	14.1	6.6	25.0
Joint pain at other location	Any	64	12	18.8	10.1	30.5	64	1	1.6	0.0	8.4
	Grade 3	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6
	Related	64	12	18.8	10.1	30.5	64	1	1.6	0.0	8.4
Muscle aches	Any	64	22	34.4	22.9	47.3	64	3	4.7	1.0	13.1
	Grade 3	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6
	Related	64	22	34.4	22.9	47.3	64	1	1.6	0.0	8.4
Shivering	Any	64	12	18.8	10.1	30.5	64	2	3.1	0.4	10.8
	Grade 3	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6
	Related	64	12	18.8	10.1	30.5	64	2	3.1	0.4	10.8
Sweating	Any	64	8	12.5	5.6	23.2	64	4	6.3	1.7	15.2
	Grade 3	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6
	Related	64	8	12.5	5.6	23.2	64	4	6.3	1.7	15.2
Temperature/(Axillary)	≥37.5°C	64	1	1.6	0.0	8.4	64	0	0.0	0.0	5.6
	≥39°C	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6
	Related	64	1	1.6	0.0	8.4	64	0	0.0	0.0	5.6

Across doses											
Fatigue	Any	65	38	58.5	45.6	70.6	66	30	45.5	33.1	58.2
	Grade 3	65	2	3.1	0.4	10.7	66	2	3.0	0.4	10.5
	Related	65	35	53.8	41.0	66.3	66	27	40.9	29.0	53.7
Headache	Any	65	37	56.9	44.0	69.2	66	22	33.3	22.2	46.0
	Grade 3	65	1	1.5	0.0	8.3	66	0	0.0	0.0	5.4
	Related	65	35	53.8	41.0	66.3	66	18	27.3	17.0	39.6
Joint pain at other location	Any	65	22	33.8	22.6	46.6	66	5	7.6	2.5	16.8
	Grade 3	65	1	1.5	0.0	8.3	66	1	1.5	0.0	8.2
	Related	65	21	32.3	21.2	45.1	66	3	4.5	0.9	12.7
Muscle aches	Any	65	32	49.2	36.6	61.9	66	9	13.6	6.4	24.3
	Grade 3	65	1	1.5	0.0	8.3	66	1	1.5	0.0	8.2
	Related	65	31	47.7	35.1	60.5	66	6	9.1	3.4	18.7
Shivering	Any	65	17	26.2	16.0	38.5	66	7	10.6	4.4	20.6
	Grade 3	65	0	0.0	0.0	5.5	66	1	1.5	0.0	8.2
	Related	65	17	26.2	16.0	38.5	66	7	10.6	4.4	20.6
Sweating	Any	65	15	23.1	13.5	35.2	66	12	18.2	9.8	29.6
	Grade 3	65	0	0.0	0.0	5.5	66	1	1.5	0.0	8.2
	Related	65	15	23.1	13.5	35.2	66	12	18.2	9.8	29.6
Temperature/(Axillary)	≥37.5°C	65	3	4.6	1.0	12.9	66	2	3.0	0.4	10.5
	≥39°C	65	0	0.0	0.0	5.5	66	0	0.0	0.0	5.4
	Related	65	2	3.1	0.4	10.7	66	2	3.0	0.4	10.5

N= number of subjects with at least one documented dose
n/%= number/percentage of subjects reporting at least once the symptom
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit
Any= occurrence of any general symptom regardless of intensity grade and relationship to vaccination
Grade 3= general symptom that prevented normal activities
Related= general symptom assessed by the investigator as causally related to the study vaccination

Secondary Outcome Variable(s): Number of days with any general symptoms during the solicited post-vaccination period (Days 0-6) (Total Vaccinated cohort)

Solicited symptom	**Dose**	**Group**	**N**	**Mean**	**Median**
Fatigue	Dose 1	Flu 1	31	2.6	2.0
		Flu 2	22	3.0	2.0
	Dose 2	Flu 1	28	2.5	2.0
		Flu 2	15	2.5	2.0
	Across doses	Flu 1	59	2.5	2.0
		Flu 2	37	2.8	2.0
Headache	Dose 1	Flu 1	25	2.3	2.0
		Flu 2	16	1.9	1.5
	Dose 2	Flu 1	21	2.0	1.0
		Flu 2	10	1.8	2.0
	Across doses	Flu 1	46	2.2	2.0
		Flu 2	26	1.8	2.0
Joint pain at other location	Dose 1	Flu 1	13	1.8	1.0
		Flu 2	4	1.5	1.0
	Dose 2	Flu 1	12	1.9	2.0
		Flu 2	1	2.0	2.0
	Across doses	Flu 1	25	1.9	2.0
		Flu 2	5	1.6	1.0
Muscle aches	Dose 1	Flu 1	17	2.6	2.0
		Flu 2	6	2.0	2.0
	Dose 2	Flu 1	22	2.1	2.0
		Flu 2	3	1.3	1.0
	Across doses	Flu 1	39	2.3	2.0

		Flu 2	9	1.8	2.0
Sweating	Dose 1	Flu 1	9	2.6	2.0
		Flu 2	9	2.8	2.0
	Dose 2	Flu 1	8	2.5	2.0
		Flu 2	4	2.3	2.0
	Across doses	Flu 1	17	2.5	2.0
		Flu 2	13	2.6	2.0
Shivering	Dose 1	Flu 1	9	1.4	1.0
		Flu 2	6	2.7	1.5
	Dose 2	Flu 1	12	1.5	1.0
		Flu 2	2	2.0	2.0
	Across doses	Flu 1	21	1.5	1.0
		Flu 2	8	2.5	1.5
Temperature	Dose 1	Flu 1	2	1.5	1.5
		Flu 2	2	1.5	1.5
	Dose 2	Flu 1	1	1.0	1.0
	Across doses	Flu 1	3	1.3	1.0
		Flu 2	2	1.5	1.5

N = number of doses with the symptom

Secondary Outcome Variable(s): Number (%) of subjects with adverse events of specific interest (AESIs) / potential Immune-Mediated Disease (pIMDs) up to Day 21 (Total Vaccinated cohort) – interim analysis posted at Day 21

AESIs/pIMDs	**Flu 1 Group N = 65**	**Flu 2 Group N = 66.**
Subjects with any AESI(s), n (%)	0 (0.0)	0 (0.0)

Note: this interim analysis is superseded by the final analysis.

Secondary Outcome Variable(s): Number (%) of subjects with adverse events of specific interest (AESIs) / potential Immune-Mediated Disease (pIMDs) up to Day 42 (Total Vaccinated cohort) – interim analysis posted at Day 42

AESIs/pIMDs	**Flu 1 Group N = 65**	**Flu 2 Group N = 66.**
Subjects with any AESI(s), n (%)	0 (0.0)	0 (0.0)

Note: this interim analysis is superseded by the final analysis.

Secondary Outcome Variable(s): Number (%) of subjects with adverse events of specific interest (AESIs) / potential Immune-Mediated Disease (pIMDs) up to Month 12 (Total Vaccinated cohort)

AESIs/pIMDs	**Flu 1 Group N = 65**	**Flu 2 Group N = 66.**
Subjects with any AESI(s), n (%)	0 (0.0)	0 (0.0)

Safety results: Number (%) of subjects with unsolicited adverse events during the 21-day follow-up period after first vaccination (Total Vaccinated cohort)

Most frequent adverse events - On-Therapy (occurring within Day 0-20 following vaccination)	**Flu 1 Group N = 65**	**Flu 2 Group N = 66**
Subjects with any AE(s), n (%)	25 (38.5)	25 (37.9)
Subjects with grade 3 AE(s), n (%)	1 (1.5)	3 (4.5)
Subjects with related AE(s), n (%)	11 (16.9)	7 (10.6)
----------*	1 (1.5)	2 (3.0)
Palpitations	-	1 (1.5)
Abdominal pain upper	1 (1.5)	1 (1.5)
Diarrhoea	1 (1.5)	1 (1.5)
Gastrointestinal disorder	1 (1.5)	-
Nausea	1 (1.5)	2 (3.0)
Palatitis	1 (1.5)	-
Fatigue	1 (1.5)	3 (4.5)
Feeling hot	-	1 (1.5)
Influenza like illness	1 (1.5)	-
Injection site induration	1 (1.5)	-

Injection site pain	-	1 (1.5)
Injection site reaction	-	1 (1.5)
Injection site warmth	1 (1.5)	-
Malaise	1 (1.5)	-
Cystitis	1 (1.5)	-
Gastroenteritis	2 (3.1)	1 (1.5)
Rhinitis	1 (1.5)	3 (4.5)
Tonsillitis	-	1 (1.5)
Upper respiratory tract infection	10 (15.4)	5 (7.6)
Muscle strain	1 (1.5)	-
Open wound	-	1 (1.5)
Decreased appetite	-	1 (1.5)
Back pain	1 (1.5)	1 (1.5)
Muscular weakness	1 (1.5)	-
Myositis	1 (1.5)	-
Neck pain	1 (1.5)	-
Sensation of heaviness	-	1 (1.5)
Tendonitis	-	1 (1.5)
Dizziness	1 (1.5)	-
Headache	-	1 (1.5)
Syncope	1 (1.5)	-
Insomnia	1 (1.5)	-
Breast pain	1 (1.5)	-
Breast swelling	1 (1.5)	-
Nasal congestion	1 (1.5)	1 (1.5)
Oropharyngeal pain	-	1 (1.5)
Pruritus	-	1 (1.5)
Pruritus generalised	-	1 (1.5)
-: adverse event absent Grade 3= event that prevented normal activities Related= event assessed by the investigator as causally related to the study vaccination * AE not yet classified by MedDRA Preferred Term		
Safety results: Number (%) of subjects with unsolicited adverse events during the 42-day follow-up period after first vaccination and the 21-day follow-up period after the second vaccination (Total Vaccinated cohort) – interim analysis posted at Day 42		
Most frequent adverse events - On-Therapy (occurring within Day 0-41 following vaccination)	**Flu 1 Group N = 65**	**Flu 2 Group N = 66**
Subjects with any AE(s), n (%)	42 (64.6)	33 (50.0)
Subjects with grade 3 AE(s), n (%)	4 (6.2)	4 (6.1)
Subjects with related AE(s), n (%)	15 (23.1)	11 (16.7)
Upper respiratory tract infection	11 (16.9)	6 (9.1)
Rhinitis	-	6 (9.1)
Gastroenteritis	4 (6.2)	1 (1.5)
Nausea	2 (3.1)	3 (4.5)
Back pain	2 (3.1)	2 (3.0)
Headache	3 (4.6)	1 (1.5)
Influenza like illness	2 (3.1)	2 (3.0)
Arthralgia	2 (3.1)	1 (1.5)
Fatigue	-	3 (4.5)
Malaise	2 (3.1)	1 (1.5)
Insomnia	2 (3.1)	-
Productive cough	-	2 (3.0)
Syncope	2 (3.1)	-
Abdominal pain upper	-	1 (1.5)

Decreased appetite	-	1 (1.5)
Deep vein thrombosis	-	1 (1.5)
Diarrhoea	-	1 (1.5)
Dizziness	-	1 (1.5)
Feeling hot	-	1 (1.5)
Gastrointestinal disorder	-	1 (1.5)
Injection site haemorrhage	-	1 (1.5)
Injection site pain	-	1 (1.5)
Injection site reaction	-	1 (1.5)
Nasal congestion	-	1 (1.5)
Open wound	-	1 (1.5)
Oropharyngeal pain	-	1 (1.5)
Palpitations	-	1 (1.5)
Procedural pain	-	1 (1.5)
Pruritus	-	1 (1.5)
Pruritus generalised	-	1 (1.5)
Rash	-	1 (1.5)
Sensation of heaviness	-	1 (1.5)
Tendonitis	-	1 (1.5)
Tonsillitis	-	1 (1.5)
Tooth abscess	-	1 (1.5)
Toothache	-	1 (1.5)
Wound	-	1 (1.5)
-: adverse event absent or not meeting the selected rule: more than 30 patients per treatment group and ≤ 3 groups: display the most frequent 10 adverse events in each group Grade 3= event that prevented normal activities Related= event assessed by the investigator as causally related to the study vaccination *Note: this interim analysis is superseded by the final analysis.*		
Safety results: Number (%) of subjects with unsolicited adverse events during the 84-day follow-up period after first vaccination and the 63-day follow-up period after the second vaccination (Total Vaccinated cohort)		
Most frequent adverse events - On-Therapy (occurring within Day 0-83 following first vaccination, within Day 0-62 following second vaccination)	**Flu 1 Group N = 65**	**Flu 2 Group N = 66**
Subjects with any AE(s), n (%)	48 (73.8)	39 (59.1)
Subjects with grade 3 AE(s), n (%)	7 (10.8)	9 (13.6)
Subjects with related AE(s), n (%)	15 (23.1)	10 (15.2)
Upper respiratory tract infection	14 (21.5)	7 (10.6)
Headache	6 (9.2)	4 (6.1)
Rhinitis	3 (4.6)	6 (9.1)
Gastroenteritis	4 (6.2)	2 (3.0)
Nausea	3 (4.6)	3 (4.5)
Arthralgia	2 (3.1)	3 (4.5)
Influenza like illness	2 (3.1)	3 (4.5)
Back pain	2 (3.1)	2 (3.0)
Fatigue	-	4 (6.1)
Pyrexia	2 (3.1)	2 (3.0)
Insomnia	3 (4.6)	-
Diarrhoea	2 (3.1)	-
Dizziness	2 (3.1)	-
Malaise	2 (3.1)	-
Oropharyngeal pain	2 (3.1)	-
Procedural pain	-	2 (3.0)
Productive cough	-	2 (3.0)
Sinusitis	-	2 (3.0)

Syncope	2 (3.1)	-
-: adverse event absent or not meeting the selected rule: more than 30 patients per treatment group and ≤ 3 groups: display the most frequent 10 adverse events in each group Grade 3= event that prevented normal activities Related= event assessed by the investigator as causally related to the study vaccination		
Safety results: Number (%) of subjects with serious adverse events up to Day 21 (Total Vaccinated cohort) – interim analysis posted at Day 21		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**Flu 1 Group N= 65**	**Flu 2 Group N= 66**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**Flu 1 Group N= 65**	**Flu 2 Group N= 66**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Note: this interim analysis is superseded by the final analysis.		
Safety results: Number (%) of subjects with serious adverse events up to Day 42 (Total Vaccinated cohort) – interim analysis posted at Day 42		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**Flu 1 Group N= 65**	**Flu 2 Group N= 66**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**Flu 1 Group N= 65**	**Flu 2 Group N= 66**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Note: this interim analysis is superseded by the final analysis.		
Safety results: Number (%) of subjects with serious adverse events up to Month 12 (Total Vaccinated cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**Flu 1 Group N= 65**	**Flu 2 Group N= 66**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	4 (6.2) [0]	4 (6.1) [0]
Abortion spontaneous complete	1 (1.5) [0]	0 (0.0) [0]
Asthma	0 (0.0) [0]	1 (1.5) [0]
Balance disorder	1 (1.5) [0]	0 (0.0) [0]
Benign prostatic hyperplasia	0 (0.0) [0]	1 (1.5) [0]
Breast cancer	1 (1.5) [0]	0 (0.0) [0]
Calculus ureteric	0 (0.0) [0]	1 (1.5) [0]
Ligament rupture	0 (0.0) [0]	1 (1.5) [0]
Nephrolithiasis	0 (0.0) [0]	1 (1.5) [0]
Open wound	1 (1.5) [0]	0 (0.0) [0]
Radius fracture	0 (0.0) [0]	1 (1.5) [0]
Renal disorder	1 (1.5) [0]	0 (0.0) [0]
Sepsis	1 (1.5) [0]	0 (0.0) [0]
Fatal SAEs	**Flu 1 Group N= 65**	**Flu 2 Group N= 66**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]

Conclusion:

21 days after the first dose, the seroconversion rate for HI antibodies against Flu A/CAL/7/09 (H1N1) was 93.8% in the Flu 1 Group and 69.8% in the Flu 2 Group. At this time point, 93.8% of the subjects in Flu 1 Group and 73.0% of the subjects in Flu 2 Group had HI antibody titres commonly accepted as indicating seroprotection and the SCF values were 44.4 and 11.4, respectively.

Up to Day 21, 25 (38.5%) subjects in the Flu 1 Group and 25 (37.9%) subjects in the Flu 2 Group reported at least one unsolicited AE. Up to Day 83, 48 (73.8%) subjects in the Flu 1 Group and 39 (59.1%) subjects in the Flu 2 Group reported at least one unsolicited AE. Each group reported 4 SAEs up to Month 12, all of which were assessed by the investigator as not related to the study vaccination. No fatal SAEs were reported during the entire study period.

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