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.: 107495 (H5N1-012)

Title: Reactogenicity and immunogenicity study of a prime-boost concept of GlaxoSmithKline Biologicals pandemic influenza vaccine (GSK1562902A) administered according to different vaccination schedules.

Rationale: The purpose of this study was to evaluate the safety and immunogenicity of the booster dose of a candidate pandemic influenza vaccine in subjects primed with the same candidate vaccine formulated from a heterologous strain. In this study, 2 different strains of the influenza candidate vaccine A/Vietnam/1194/2004 and A/Indonesia/05/2005 were used.
VT: GlaxoSmithKline (GSK) Biologicals' pandemic influenza candidate vaccine containing A/Vietnam/1994/2004 strain
IN: GSK Biologicals' pandemic influenza candidate vaccine containing A/Indonesia/05/2005 strain

Phase: II

Study Period: 5 February 2007 to 20 October 2008

Study Design: Open, randomized, multicentered study with 8 parallel groups (1:1:1:1:1:1:1:1)

Centers: 10 centers in Germany.

Indication: Immunization against influenza disease during pandemic in subjects aged 18 to 60 years.

Treatment: There were 8 parallel treatment groups:

- VT/VT/6 group: subjects received 2 doses of vaccine formulated from VT strain, 1 at Day 0 and 1 at Month 6.
- VT/VT/12 group: subjects received 2 doses of vaccine formulated from VT strain, 1 at Day 0 and 1 at Month 12.
- VT/IN/6 group: subjects received 1 dose of vaccine formulated from VT strain at Day 0 and 1 dose of the vaccine including IN at Month 6.
- VT/IN/12 group: subjects received 1 dose of vaccine formulated from VT strain at Day 0 and 1 dose of the vaccine including IN strain at Month 12.
- 2VT/VT/6 group: subjects received 2 doses of vaccine formulated from VT strain, 1 at Day 0 and 1 at Day 21 and a 3rd dose of vaccine including VT strain at Month 6.
- 2VT/VT/12 group: subjects received 2 doses of vaccine formulated from VT strain, 1 at Day 0 and 1 at Day 21 and a 3rd dose of vaccine including VT strain at Month 12.
- 2VT/IN/6 group: subjects received 2 doses of vaccine formulated from VT strain, 1 at Day 0 and 1 at Day 21 and a 3rd dose of vaccine including IN strain at Month 6.
- 2VT/IN/12 group: subjects received 2 doses of vaccine formulated from VT strain, 1 at Day 0 and 1 at Day 21 and a 3rd dose of vaccine including IN strain at Month 12.

The vaccines were administered in the deltoid region of the non-dominant arm.

Objectives:

- To assess if the humoral immune response induced by a booster dose of the candidate vaccine given 6 months after primary vaccination with a single dose of the candidate vaccine formulated from a heterologous strain fulfils the criteria established for influenza vaccines by the European Committee for Medicinal Products for Human Use (CHMP).
- To evaluate the safety of the candidate vaccine in terms of solicited local and general symptoms, unsolicited symptoms and serious adverse events.

Primary Outcome/Efficacy Variable:

Immunogenicity:

For humoral immune response:

Observed variables at Day 0, Month 6, Month 6 + 7 Days, Month 6 + 21 Days H5N1 haemagglutination inhibition (HI) antibody titers against the A/Indonesia/05/2005 strain, in the VT/IN/6 group.

Derived variables (with 95% confidence intervals [CIs]):

- Geometric mean titers (GMTs) of H5N1 HI antibody titers at Day 0, Month 6, Month 6 + 7 Days, Month 6 + 21 Days.
- Seroconversion rates* (SCR) at Month 6, Month 6 + 7 days, Month 6 + 21 days.
- Seroconversion factors** (SCF) at Month 6, Month 6 + 7 days, Month 6 + 21 days.
- Seroprotection rates*** (SPR) at Day 0, Month 6, Month 6 + 7 days, Month 6 + 21 days.

The following outcome measures were not in the protocol, but are addressed here for matter of completeness:

- Booster seroconversion rates**** (Booster SCR) at Month 6 + 7 days and Month 6 + 21 days.
- Booster Factor***** (BF) at Month 6 + 7 days, Month 6 + 21 days.

*SCR was defined as the percentage of vaccinees that had either a pre-vaccination titer at Day 0 before any priming dose < 1:10 and a post-vaccination titer ≥ 1:40 or a pre-vaccination titer ≥ 1:10 and at least a 4-fold increase in post-vaccination

H5N1 HI antibodies
**SCF was defined as the fold increase in H5N1 HI antibody GMTs post-vaccination compared to Day 0)
***SPR was defined as the percentage of vaccinees with an H5N1 HI antibody titer ≥ 1:40
****Booster SCR (Booster Response) : the same calculation was made as for the SCR using the pre-booster HI antibody titers as the baseline value
*****Booster Factor was defined as the fold-increase in H5N1 HI antibodies between the pre- and post-booster vaccination time-points

Safety:

- Percentage, intensity and relationship to vaccination of solicited local and general signs and symptoms during a 7-day follow-up period (i.e. day of vaccination and 6 subsequent days) after each vaccination and overall.
- Percentage, intensity and relationship to vaccination of unsolicited local and general signs and symptoms during a 30-day follow-up period after primary vaccination(s) and booster vaccination, and overall.
- Occurrence of serious adverse events (SAEs) during the entire study.

Secondary Outcome/Efficacy Variable(s):

Immunogenicity:

For the humoral immune response in terms of H5N1 HI antibodies against the A/Indonesia/05/2005 strain (in the remaining groups) and against the A/Vietnam/1194/2004 strain, the following parameters (with 95% confidence intervals [CIs]) were calculated at the applicable time points, depending on the vaccination schedule:

- GMTs at Day 0, Day 21, Day 42 (if two primary doses), Month 6, Month 6+ 7 days, Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.
- SCR* at Day 21, Day 42 (if two primary doses), Month 6, Month 6 + 7 days, Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.
- SCF* at Day 21, Day 42 (if two primary doses), Month 6, Month 6 + 7 days, Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.
- SPR* at Day 0, Day 21, Day 42 (if two primary doses), Month 6, Month 6 + 7 days, Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.

The following outcome measures were not in the protocol, but are addressed here for matter of completeness:

- Booster SCR* at Month 6 + 7 days and Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.
- BF* at Month 6, Month 6 + 7 days, Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.

For the humoral immune response in terms of H5N1 neutralizing antibodies, the following parameters (with 95% CIs) were calculated:

- GMTs at Day 0, Day 21, Day 42 (if two primary doses), Month 6, Month 6 + 7 days, Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.
- SCR#; at Day 21, Day 42 (if two primary doses), Month 6, Month 6 + 7 days, Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.

#SCR for neutralizing antibody defined as the percentage of vaccinees with a minimum 4-fold increase in neutralizing antibody titer at the post-vaccination time-point compared to Day 0)

The following outcome measure was not in the protocol, but is addressed here for matter of completeness:

- Booster SCR* at Month 6 + 7 days and Month 6 + 21 days, Month 12, Month 12 + 7 Days (for subjects who received a booster dose at Month 12), Month 12 + 21 Days (for subjects who received a booster dose at Month 12) and at Month 18.

*Please refer to the primary outcome measures for the definition.

For the cell-mediated immunogenicity (CMI) response (interferon-γ [IFN-γ], interleukin-2 [IL-2], cluster of differentiation-40 ligand [CD40L], tumor necrosis factor alpha [TNF-α]), the following parameters (with 95% CIs) were calculated at Day 0, Month 6/12, Month 6/12 + 7 Days, Month 6/12 + 21 Days and Month 18 in each group:

- Frequency of influenza-specific CD4/CD8 T-cells per 10^6 in tests producing at least two different cytokines (CD40L, IL-2, TNF-α, IFN-γ)
- Frequency of influenza-specific CD4/CD8 T-cells per 10^6 in tests producing at least CD40L and another signal molecule (IL-2, IFN-γ, TNF-α)
- Frequency of influenza-specific CD4/CD8 T-cells per 10^6 in tests producing at least IL-2 and another signal molecule (CD40L, IFN-γ, TNF-α)
- Frequency of influenza-specific CD4/CD8 T-cells per 10^6 in tests producing at least TNF-α and another signal molecule (IL-2, IFN-γ, CD40L)

Statistical Methods:

The analyses were performed on the Total Vaccinated Cohort, the ATP (According to Protocol) Cohort for immunogenicity and the ATP cohort for persistence.

- The Total vaccinated Cohort included all vaccinated subjects for whom data were available.
- The ATP Cohort for immunogenicity included all evaluable subjects for whom immunogenicity data were available and who complied with the inclusion/exclusion criteria as defined in the protocol
- The ATP Cohort for persistence included all evaluable subjects for whom long term immunogenicity data were available and who complied with the inclusion/exclusion criteria as defined in the protocol

Analysis of immunogenicity:

The analysis was performed on the ATP Cohort for immunogenicity and on the ATP cohort for persistence.

Descriptive analysis:

For each treatment group, at each applicable time point for the humoral immune response, the GMTs, seropositivity, SCR, SCF, SPR, booster SCR and BF were calculated with 95%CI . For humoral immune response in terms of neutralizing antibodies, GMTs, seropositivity, SCR and booster SCR were calculated with 95%CI for each time-point.

The frequency of influenza-specific immune marker-positive CD4/CD8 T-lymphocytes was summarized (descriptively) for each test for the A/Indonesia and A/Vietnam strains.

Analysis of safety:

The analysis was performed on the Total Vaccinated Cohort.

The percentage of subject reporting each individual solicited local and general symptom during the 7-day (day 0-6) solicited follow-up period after vaccination was tabulated with exact 95% CI after each vaccination and overall. The same tabulation was performed for grade 3 symptoms and general symptoms assessed by the investigators as having a relationship to vaccination. The percentage of subjects with at least one report of unsolicited adverse events classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred terms and reported up to 31 days (day 0-30) after primary and booster vaccination was tabulated. The same tabulation was performed for grade 3 AEs and for AEs assessed by the investigators as having a causal relationship to vaccination. The occurrence of SAEs during the entire study period was tabulated according to MedDRA preferred terms.

Study Population: Healthy male or female between the ages of 18-60 years at the time of first vaccination. If the subject is female, she must be of non-childbearing potential. Written informed consent was obtained from all the subjects before enrollment in the study.

Number of subjects	**VT/IN/6 Group**	**VT/VT/6 Group**	**2VT/IN/6 Group**	**2VT/VT/ 6 Group**	**VT/IN/12 Group**	**VT/VT/12 Group**	**2VT/IN/12 Group**	**2VT/VT/12 Group**
Planned, N	63	63	63	63	63	63	63	63
Randomized, N (Total Vaccinated Cohort)	63	66	64	63	64	64	65	63
Completed to Month 18, n (%)	52 (82.5)	57 (86.4)	61 (95.3)	55 (87.3)	59 (92.2)	59 (92.2)	55 (84.6)	51 (81.0)
Total Number Subjects Withdrawn (Month 18), n (%)	11 (17.5)	9 (13.6)	3 (4.7)	8 (12.7)	5 (7.8)	5 (7.8)	10 (15.4)	12 (19.0)
Withdrawn due to Adverse Events (Month 18), n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.1)	1 (1.5)	0 (0.0)
Withdrawn due to Lack of	NA	NA	NA	NA	NA	NA	NA	NA

Efficacy (Month 18), n (%)								
Withdrawn for other reasons (Month 18), n (%)	11 (17.5)	9 (13.6)	3 (4.7)	8 (12.7)	5 (7.8)	3 (4.7)	9 (13.8)	12 (19.0)
Demographics	**VT/IN/6 Group**	**VT/VT/6 Group**	**2VT/IN/6 Group**	**2VT/VT/ 6 Group**	**VT/IN/1 2 Group**	**VT/VT/1 2 Group**	**2VT/IN/1 2 Group**	**2VT/VT/12 Group**
N (Total Vaccinated Cohort)	63	66	64	63	64	64	65	63
Females: Males	32:31	35:31	33:31	37:26	37:27	27:37	36:29	36:27
Mean Age, years (SD)	34.6 (12.94)	33.1 (11.39)	33.8 (11.80)	33.4 (12.41)	34.6 (12.92)	34.8 (12.90)	33.2 (11.18)	34.3 (11.63)
Caucasian / European heritage, n (%)	63 (100)	64 (97.0)	62 (96.9)	61 (96.8)	64 (100)	61 (95.3)	63 (96.9)	62 (98.4)

NA= Not Applicable

Primary Efficacy Results: Seropositivity rates and GMTs for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 6 + 21 days, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:10**				**GMT**		
				n	**%**	**95%CI**		**value**	**95%CI**	
						LL	**UL**		**LL**	**UL**
A/Indonesia	VT/IN/6*	PRE	56	0	0.0	0.0	6.4	5.0	5.0	5.0
		PI(D21)	56	8	14.3	6.4	26.2	6.3	5.4	7.4
		PI(M6)	55	4	7.3	2.0	17.6	5.5	5.0	6.0
		PII(M6+D7)	53	52	98.1	89.9	100	152.9	112.2	208.2
		PII(M6+D21)	52	51	98.1	89.7	100	303.4	215.7	426.6
	VT/VT/6	PRE	55	0	0.0	0.0	6.5	5.0	5.0	5.0
		PI(D21)	55	7	12.7	5.3	24.5	5.6	5.1	6.0
		PI(M6)	49	2	4.1	0.5	14.0	5.3	4.9	5.7
		PII(M6+D7)	47	37	78.7	64.3	89.3	64.6	41.3	101.1
		PII(M6+D21)	48	41	85.4	72.2	93.9	92.4	61.1	139.9
	2VT/IN/6	PRE	50	0	0.0	0.0	7.1	5.0	5.0	5.0
		PI(D21)	50	6	12.0	4.5	24.3	6.2	5.2	7.4
		PII(D42)	44	27	61.4	45.5	75.6	23.6	15.6	35.7
		PII(M6)	49	18	36.7	23.4	51.7	8.6	6.6	11.3
		PIII(M6+D7)	47	41	87.2	74.3	95.2	120.0	76.8	187.6
		PIII(M6+D21)	49	47	95.9	86.0	99.5	392.9	256.7	601.4
	2VT/VT/6	PRE	48	0	0.0	0.0	7.4	5.0	5.0	5.0
		PI(D21)	48	5	10.4	3.5	22.7	5.5	5.0	6.0
		PII(D42)	41	22	53.7	37.4	69.3	18.4	11.9	28.3
		PII(M6)	48	13	27.1	15.3	41.8	7.2	6.0	8.6
		PIII(M6+D7)	45	37	82.2	67.9	92.0	65.0	42.1	100.2
		PIII(M6+D21)	46	41	89.1	76.4	96.4	127.7	83.8	194.6
A/Vietnam	VT/IN/6	PRE	56	0	0.0	0.0	6.4	5.0	5.0	5.0
		PI(D21)	56	31	55.4	41.5	68.7	20.9	14.1	30.9
		PI(M6)	55	25	45.5	32.0	59.4	12.0	8.9	16.1
		PII(M6+D7)	53	52	98.1	89.9	100	226.3	168.3	304.3
		PII(M6+D21)	52	51	98.1	89.7	100	434.7	314.8	600.5
	VT/VT/6	PRE	55	2	3.6	0.4	12.5	5.3	4.9	5.7
		PI(D21)	55	28	50.9	37.1	64.6	16.3	11.5	23.2
		PI(M6)	49	18	36.7	23.4	51.7	9.7	7.4	12.7
		PII(M6+D7)	47	42	89.4	76.9	96.5	202.6	130.7	314.1
		PII(M6+D21)	48	43	89.6	77.3	96.5	287.2	180.3	457.5
	2VT/IN/6	PRE	50	1	2.0	0.1	10.6	5.2	4.8	5.7
		PI(D21)	50	33	66.0	51.2	78.8	33.6	21.4	52.8
		PII(D42)	44	41	93.2	81.3	98.6	229.8	153.6	344.0

		PII(M6)	49	35	71.4	56.7	83.4	29.9	20.1	44.4
		PIII(M6+D7)	47	43	91.5	79.6	97.6	182.7	118.5	281.7
		PIII(M6+D21)	49	47	95.9	86.0	99.5	571.4	366.3	891.3
	2VT/VT/6	PRE	48	2	4.2	0.5	14.3	5.7	4.7	7.0
		PI(D21)	48	29	60.4	45.3	74.2	29.3	17.9	48.1
		PII(D42)	41	39	95.1	83.5	99.4	289.1	190.3	439.2
		PII(M6)	48	34	70.8	55.9	83.0	32.0	21.3	48.0
		PIII(M6+D7)	45	41	91.1	78.8	97.5	224.5	144.9	347.7
		PIII(M6+D21)	46	43	93.5	82.1	98.6	380.5	240.2	602.9

GMT = Geometric Mean antibody Titer
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:10)
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
*Primary outcome variable

Primary Efficacy Results: SCR for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 6 + 21 days, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Indonesia	VT/IN/6*	PI(D21)	56	3	5.4	1.1	14.9
		PI(M6)	55	0	0.0	0.0	6.5
		PII(M6+D7)	53	49	92.5	81.8	97.9
		PII(M6+D21)	52	51	98.1	89.7	100
	VT/VT/6	PI(D21)	55	0	0.0	0.0	6.5
		PI(M6)	49	0	0.0	0.0	7.3
		PII(M6+D7)	47	35	74.5	59.7	86.1
		PII(M6+D21)	48	40	83.3	69.8	92.5
	2VT/IN/6	PI(D21)	50	3	6.0	1.3	16.5
		PII(D42)	44	24	54.5	38.8	69.6
		PII(M6)	49	5	10.2	3.4	22.2
		PIII(M6+D7)	47	40	85.1	71.7	93.8
		PIII(M6+D21)	49	46	93.9	83.1	98.7
	2VT/VT/6	PI(D21)	48	0	0.0	0.0	7.4
		PII(D42)	41	17	41.5	26.3	57.9
		PII(M6)	48	2	4.2	0.5	14.3
		PIII(M6+D7)	45	33	73.3	58.1	85.4
		PIII(M6+D21)	46	40	87.0	73.7	95.1
A/Vietnam	VT/IN/6	PI(D21)	56	25	44.6	31.3	58.5
		PI(M6)	55	14	25.5	14.7	39.0
		PII(M6+D7)	53	52	98.1	89.9	100
		PII(M6+D21)	52	51	98.1	89.7	100
	VT/VT/6	PI(D21)	55	21	38.2	25.4	52.3
		PI(M6)	49	6	12.2	4.6	24.8
		PII(M6+D7)	47	42	89.4	76.9	96.5
		PII(M6+D21)	48	43	89.6	77.3	96.5
	2VT/IN/6	PI(D21)	50	30	60.0	45.2	73.6

		PII(D42)	44	41	93.2	81.3	98.6
		PII(M6)	49	26	53.1	38.3	67.5
		PIII(M6+D7)	47	42	89.4	76.9	96.5
		PIII(M6+D21)	49	46	93.9	83.1	98.7
	2VT/VT/6	PI(D21)	48	24	50.0	35.2	64.8
		PII(D42)	41	38	92.7	80.1	98.5
		PII(M6)	48	27	56.3	41.2	70.5
		PIII(M6+D7)	45	39	86.7	73.2	94.9
		PIII(M6+D21)	46	42	91.3	79.2	97.6

Seroconversion defined as:
For initially seronegative subjects (at day 0), antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects (at day 0), antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
*Primary outcome variable

Primary Efficacy Results: SCF for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 6 + 21 days, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCF**		
				Value	**95% CI**	
					LL	**UL**
A/Indonesia	VT/IN/6*	PI(D21)	56	1.3	1.1	1.5
		PI(M6)	55	1.1	1.0	1.2
		PII(M6+D7)	53	30.6	22.4	41.6
		PII(M6+D21)	52	60.7	43.1	85.3
	VT/VT/6	PI(D21)	55	1.1	1.0	1.2
		PI(M6)	49	1.1	1.0	1.1
		PII(M6+D7)	47	12.9	8.3	20.2
		PII(M6+D21)	48	18.5	12.2	28.0
	2VT/IN/6	PI(D21)	50	1.2	1.0	1.5
		PII(D42)	44	4.7	3.1	7.1
		PII(M6)	49	1.7	1.3	2.3
		PIII(M6+D7)	47	24.0	15.4	37.5
		PIII(M6+D21)	49	78.6	51.3	120.3
	2VT/VT/6	PI(D21)	48	1.1	1.0	5.7
		PII(D42)	41	3.7	2.4	1.7
		PII(M6)	48	1.4	1.2	1.7
		PIII(M6+D7)	45	13.0	8.4	20.0
		PIII(M6+D21)	46	25.5	16.8	38.9
A/Vietnam	VT/IN/6	PI(D21)	56	4.2	2.8	6.2
		PI(M6)	55	2.4	1.8	3.2
		PII(M6+D7)	53	45.3	33.7	60.9
		PII(M6+D21)	52	86.9	63.0	120.1
	VT/VT/6	PI(D21)	55	3.1	2.2	4.3
		PI(M6)	49	1.8	1.4	2.4
		PII(M6+D7)	47	38.2	24.5	59.7
		PII(M6+D21)	48	54.2	33.8	87.1

	2VT/IN/6	PI(D21)	50	6.5	4.2	10.0
		PII(D42)	44	43.8	29.3	65.6
		PII(M6)	49	6.0	4.0	8.9
		PIII(M6+D7)	47	36.5	23.7	56.3
		PIII(M6+D21)	49	114.3	73.3	178.3
	2VT/VT/6	PI(D21)	48	5.1	3.3	8.0
		PII(D42)	41	49.2	32.6	74.5
		PII(M6)	48	5.6	3.8	8.2
		PIII(M6+D7)	45	38.8	24.7	60.9
		PIII(M6+D21)	46	66.0	41.2	105.7

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/D0)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21) = Post-vaccination dose 1 at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42
PI(M6) = Post-vaccination dose 1 at Month 6
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
*Primary outcome variable

Primary Efficacy Results: SPR for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 6 + 21 days, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SPR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Indonesia	VT/IN/6*	PRE	56	0	0.0	0.0	6.4
		PI(D21)	56	3	5.4	1.1	14.9
		PI(M6)	55	0	0.0	0.0	6.5
		PII(M6+D7)	53	49	92.5	81.8	97.9
		PII(M6+D21)	52	51	98.1	89.7	100
	VT/VT/6	PRE	55	0	0.0	0.0	6.5
		PI(D21)	55	0	0.0	0.0	6.5
		PI(M6)	49	0	0.0	0.0	7.3
		PII(M6+D7)	47	35	74.5	59.7	86.1
		PII(M6+D21)	48	40	83.3	69.8	92.5
	2VT/IN/6	PRE	50	0	0.0	0.0	7.1
		PI(D21)	50	3	6.0	1.3	16.5
		PII(D42)	44	24	54.5	38.8	69.6
		PII(M6)	49	5	10.2	3.4	22.2
		PIII(M6+D7)	47	40	85.1	71.7	93.8
		PIII(M6+D21)	49	46	93.9	83.1	98.7
	2VT/VT/6	PRE	48	0	0.0	0.0	7.4
		PI(D21)	48	0	0.0	0.0	7.4
		PII(D42)	41	17	41.5	26.3	57.9
		PII(M6)	48	2	4.2	0.5	14.3
		PIII(M6+D7)	45	33	73.3	58.1	85.4
		PIII(M6+D21)	46	40	87.0	73.7	95.1
A/Vietnam	VT/IN/6	PRE	56	0	0.0	0.0	6.4
		PI(D21)	56	25	44.6	31.3	58.5
		PI(M6)	55	14	25.5	14.7	39.0
		PII(M6+D7)	53	52	98.1	89.9	100
		PII(M6+D21)	52	51	98.1	89.7	100
	VT/VT/6	PRE	55	0	0.0	0.0	6.5

		PI(D21)	55	21	38.2	25.4	52.3
		PI(M6)	49	7	14.3	5.9	27.2
		PII(M6+D7)	47	42	89.4	76.9	96.5
		PII(M6+D21)	48	43	89.6	77.3	96.5
	2VT/IN/6	PRE	50	1	2.0	0.1	10.6
		PI(D21)	50	30	60.0	45.2	73.6
		PII(D42)	44	41	93.2	81.3	98.6
		PII(M6)	49	26	53.1	38.3	67.5
		PIII(M6+D7)	47	42	89.4	76.9	96.5
		PIII(M6+D21)	49	46	93.9	83.1	98.7
	2VT/VT/6	PRE	48	2	4.2	0.5	14.3
		PI(D21)	48	25	52.1	37.2	66.7
		PII(D42)	41	38	92.7	80.1	98.5
		PII(M6)	48	28	58.3	43.2	72.4
		PIII(M6+D7)	45	40	88.9	75.9	96.3
		PIII(M6+D21)	46	42	91.3	79.2	97.6

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
*Primary outcome variable

Primary Efficacy Results: Booster SCR of H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/5/2005 strains at Month 6 + 7 days, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	Group	N	Booster SCR			
			n	%	95%CI	
					LL	UL
A/Indonesia	VT/IN/6*	53	48	90.6	79.3	96.9
	VT/VT/6	47	35	74.5	59.7	86.1
	2VT/IN/6	47	40	85.1	71.7	93.8
	2VT/VT/6	45	31	68.9	53.4	81.8
A/Vietnam	VT/IN/6	53	47	88.7	77.0	95.7
	VT/VT/6	47	40	85.1	71.7	93.8
	2VT/IN/6	47	31	66.0	50.7	79.1
	2VT/VT/6	45	30	66.7	51.0	80.0

Booster SCR defined as :
For seronegative subjects at pre-booster (Month 6), antibody titer ≥ 1:40 at Month 6 + 7 days
For seropositive subjects at pre-booster (Month 6), antibody titer at Month 6 + 7 days ≥ 4 fold the pre-vaccination antibody titer at month 6
N = number of subjects with both pre- and post- booster vaccination results available
n/% = number/percentage of responders
95% CI = exact 95% confidence interval; LL = lower limit, UL = upper limit
*Primary outcome variable

Primary Efficacy Results: Booster SCR for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains at Month 6 + 21 days for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	Group	N	Booster SCR			
			n	%	95%CI	
					LL	UL

A/Indonesia	VT/IN/6*	52	51	98.1	89.7	100
	VT/VT/6	48	39	81.3	67.4	91.1
	2VT/IN/6	49	45	91.8	80.4	97.7
	2VT/VT/6	46	39	84.8	71.1	93.7
A/Vietnam	VT/IN/6	52	51	98.1	89.7	100
	VT/VT/6	48	42	87.5	74.8	95.3
	2VT/IN/6	49	44	89.8	77.8	96.6
	2VT/VT/6	46	38	82.6	68.6	92.2

Seroconversion rate Booster defined as :
For seronegative subjects at pre-booster (Month 6), antibody titer ≥ 1:40 at Month 6 + 21 days
For seropositive subjects at pre-booster (Month 6), antibody titer at Month 6 + 21 days ≥ 4 fold the pre-vaccination antibody titer at month 6
N = number of subjects with both pre- and post- booster vaccination results available
n/% = number/percentage of responders
95%CI = exact 95% confidence interval; LL = lower limit, UL = upper limit
*Primary outcome variable

Primary Efficacy Results: BF of H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains at Month 6 + 7 days for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**BF**		
				Value	**95%CI**	
					LL	**UL**
A/Indonesia	VT/IN/6*	PII(M6+D7)	53	27.9	20.4	38.3
	VT/VT/6	PII(M6+D7)	47	12.3	7.8	19.2
	2VT/IN/6	PIII(M6+D7)	47	14.5	8.7	24.3
	2VT/VT/6	PIII(M6+D7)	45	9.2	6.2	13.7
A/Vietnam	VT/IN/6	PII(M6+D7)	53	18.2	12.8	26.0
	VT/VT/6	PII(M6+D7)	47	20.3	12.7	32.5
	2VT/IN/6	PIII(M6+D7)	47	6.3	4.1	9.7
	2VT/VT/6	PIII(M6+D7)	45	6.9	4.5	10.7

N = Number of subjects with pre- and post-vaccination results available
Booster factor (BF) = Seroconversion Factor booster (mean[log10(POST/M6)])
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
* Primary outcome variable

Primary Efficacy Results: BF for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains at Month 6 + 21 days, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**BF**		
				Value	**95%CI**	
					LL	**UL**
A/Indonesia	VT/IN/6*	PII(M6+D21)	52	55.3	39.5	77.4
	VT/VT/6	PII(M6+D21)	48	17.6	11.5	26.8
	2VT/IN/6	PIII(M6+D21)	49	45.6	30.8	67.4
	2VT/VT/6	PIII(M6+D21)	46	17.9	11.9	27.0
A/Vietnam	VT/IN/6	PII(M6+D21)	52	35.4	24.5	51.1
	VT/VT/6	PII(M6+D21)	48	29.2	18.2	46.6
	2VT/IN/6	PIII(M6+D21)	49	19.1	12.4	29.4
	2VT/VT/6	PIII(M6+D21)	46	11.5	7.3	18.0

N = Number of subjects with pre- and post-vaccination results available
Booster factor (BF) = Seroconversion Factor booster (mean[log10(POST/M6)])
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
*Primary outcome variable

Primary Efficacy Results: Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total vaccinated cohort)

Groups		VT/IN/6					VT/VT/6					2VT/IN/6				
					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 1																
Ecchymosis (mm)	All	62	1	1.6	0.0	8.7	66	1	1.5	0.0	8.2	64	2	3.1	0.4	10.8
	>100 mm	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
Induration (mm)	All	62	9	14.5	6.9	25.8	66	9	13.6	6.4	24.3	64	10	15.6	7.8	26.9
	>100 mm	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
Pain	All	62	50	80.6	68.6	89.6	66	61	92.4	83.2	97.5	64	54	84.4	73.1	92.2
	Grade 3	62	2	3.2	0.4	11.2	66	2	3.0	0.4	10.5	64	0	0.0	0.0	5.6
Redness (mm)	All	62	4	6.5	1.8	15.7	66	6	9.1	3.4	18.7	64	5	7.8	2.6	17.3
	>100 mm	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
Swelling (mm)	All	62	7	11.3	4.7	21.9	66	7	10.6	4.4	20.6	64	7	10.9	4.5	21.2
	>100 mm	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
Dose 2																
Ecchymosis (mm)	All	57	1	1.8	0.0	9.4	57	0	0.0	0.0	6.3	64	0	0.0	0.0	5.6
	>100 mm	57	0	0.0	0.0	6.3	57	0	0.0	0.0	6.3	64	0	0.0	0.0	5.6
Induration (mm)	All	57	13	22.8	12.7	35.8	57	11	19.3	10.0	31.9	64	9	14.1	6.6	25.0
	>100 mm	57	1	1.8	0.0	9.4	57	0	0.0	0.0	6.3	64	0	0.0	0.0	5.6
Pain	All	57	46	80.7	68.1	90.0	57	49	86.0	74.2	93.7	64	50	78.1	66.0	87.5
	Grade 3	57	4	7.0	1.9	17.0	57	4	7.0	1.9	17.0	64	0	0.0	0.0	5.6
Redness (mm)	All	57	9	15.8	7.5	27.9	57	8	14.0	6.3	25.8	64	11	17.2	8.9	28.7
	>100 mm	57	0	0.0	0.0	6.3	57	0	0.0	0.0	6.3	64	0	0.0	0.0	5.6
Swelling (mm)	All	57	7	12.3	5.1	23.7	57	12	21.1	11.4	33.9	64	10	15.6	7.8	26.9
	>100 mm	57	1	1.8	0.0	9.4	57	0	0.0	0.0	6.3	64	0	0.0	0.0	5.6
Dose 3																
Ecchymosis (mm)	All	-	-	-	-	-	-	-	-	-	-	63	0	0.0	0.0	5.7
	>100 mm	-	-	-	-	-	-	-	-	-	-	63	0	0.0	0.0	5.7
Induration (mm)	All	-	-	-	-	-	-	-	-	-	-	63	16	25.4	15.3	37.9
	>100 mm	-	-	-	-	-	-	-	-	-	-	63	0	0.0	0.0	5.7
Pain	All	-	-	-	-	-	-	-	-	-	-	63	53	84.1	72.7	92.1
	Grade 3	-	-	-	-	-	-	-	-	-	-	63	5	7.9	2.6	17.6
Redness (mm)	All	-	-	-	-	-	-	-	-	-	-	63	8	12.7	5.6	23.5
	>100 mm	-	-	-	-	-	-	-	-	-	-	63	0	0.0	0.0	5.7
Swelling (mm)	All	-	-	-	-	-	-	-	-	-	-	63	15	23.8	14.0	36.2
	>100 mm	-	-	-	-	-	-	-	-	-	-	63	0	0.0	0.0	5.7
Across doses																
Ecchymosis (mm)	All	62	2	3.2	0.4	11.2	66	1	1.5	0.0	8.2	64	2	3.1	0.4	10.8
	>100 mm	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
Induration (mm)	All	62	17	27.4	16.9	40.2	66	13	19.7	10.9	31.3	64	22	34.4	22.9	47.3
	>100 mm	62	1	1.6	0.0	8.7	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
Pain	All	62	56	90.3	80.1	96.4	66	62	93.9	85.2	98.3	64	61	95.3	86.9	99.0
	Grade 3	62	6	9.7	3.6	19.9	66	6	9.1	3.4	18.7	64	5	7.8	2.6	17.3
Redness (mm)	All	62	11	17.7	9.2	29.5	66	8	12.1	5.4	22.5	64	16	25.0	15.0	37.4
	>100 mm	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
Swelling (mm)	All	62	12	19.4	10.4	31.4	66	15	22.7	13.3	34.7	64	21	32.8	21.6	45.7
	>100 mm	62	1	1.6	0.0	8.7	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6

Groups		2VT/VT/6				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Dose 1						
Ecchymosis	All	62	0	0.0	0.0	5.8

(mm)	>100 mm	62	0	0.0	0.0	5.8
Induration	All	62	20	32.3	20.9	45.3
(mm)	>100 mm	62	0	0.0	0.0	5.8
Pain	All	62	56	90.3	80.1	96.4
	Grade 3	62	4	6.5	1.8	15.7
Redness	All	62	8	12.9	5.7	23.9
(mm)	>100 mm	62	0	0.0	0.0	5.8
Swelling (mm)	All	62	14	22.6	12.9	35.0
	>100 mm	62	0	0.0	0.0	5.8
Dose 2						
Ecchymosis	All	61	1	1.6	0.0	8.8
(mm)	>100 mm	61	0	0.0	0.0	5.9
Induration	All	61	14	23.0	13.2	35.5
(mm)	>100 mm	61	0	0.0	0.0	5.9
Pain	All	61	49	80.3	68.2	89.4
	Grade 3	61	4	6.6	1.8	15.9
Redness	All	61	7	11.5	4.7	22.2
(mm)	>100 mm	61	0	0.0	0.0	5.9
Swelling (mm)	All	61	10	16.4	8.2	28.1
	>100 mm	61	0	0.0	0.0	5.9
Dose 3						
Ecchymosis	All	58	0	0.0	0.0	6.2
(mm)	>100 mm	58	0	0.0	0.0	6.2
Induration	All	58	13	22.4	12.5	35.3
(mm)	>100 mm	58	0	0.0	0.0	6.2
Pain	All	58	51	87.9	76.7	95.0
	Grade 3	58	5	8.6	2.9	19.0
Redness	All	58	7	12.1	5.0	23.3
(mm)	>100 mm	58	0	0.0	0.0	6.2
Swelling (mm)	All	58	13	22.4	12.5	35.3
	>100 mm	58	0	0.0	0.0	6.2
Across doses						
Ecchymosis	All	62	1	1.6	0.0	8.7
(mm)	>100 mm	62	0	0.0	0.0	5.8
Induration	All	62	25	40.3	28.1	53.6
(mm)	>100 mm	62	0	0.0	0.0	5.8
Pain	All	62	59	95.2	86.5	99.0
	Grade 3	62	10	16.1	8.0	27.7
Redness	All	62	13	21.0	11.7	33.2
(mm)	>100 mm	62	0	0.0	0.0	5.8
Swelling (mm)	All	62	22	35.5	23.7	48.7
	>100 mm	62	0	0.0	0.0	5.8

For each dose and across doses:
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
All: any symptom regardless of intensity
Grade 3 pain = pain that prevented normal activity

Primary Efficacy Results: Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall – for subjects boosted at month 12 (Total vaccinated cohort)

Groups		**VT/IN/12**					**VT/VT/12**					**2VT/IN/12**				
					95 % CI					**95 % CI**					**95 % CI**	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 1																

Ecchymosis (mm)	All	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	3	4.6	1.0	12.9
	>100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
Induration (mm)	All	64	7	10.9	4.5	21.2	64	9	14.1	6.6	25.0	65	14	21.5	12.3	33.5
	>100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
Pain	All	64	53	82.8	71.3	91.1	64	52	81.3	69.5	89.9	65	57	87.7	77.2	94.5
	Grade 3	64	5	7.8	2.6	17.3	64	5	7.8	2.6	17.3	65	2	3.1	0.4	10.7
Redness (mm)	All	64	5	7.8	2.6	17.3	64	8	12.5	5.6	23.2	65	6	9.2	3.5	19.0
	>100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
Swelling (mm)	All	64	5	7.8	2.6	17.3	64	10	15.6	7.8	26.9	65	8	12.3	5.5	22.8
	>100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
Dose 2																
Ecchymosis (mm)	All	62	0	0.0	0.0	5.8	58	2	3.4	0.4	11.9	63	1	1.6	0.0	8.5
	>100 mm	62	0	0.0	0.0	5.8	58	0	0.0	0.0	6.2	63	0	0.0	0.0	5.7
Induration (mm)	All	62	11	17.7	9.2	29.5	58	11	19.0	9.9	31.4	63	9	14.3	6.7	25.4
	>100 mm	62	0	0.0	0.0	5.8	58	0	0.0	0.0	6.2	63	0	0.0	0.0	5.7
Pain	All	62	54	87.1	76.1	94.3	58	47	81.0	68.6	90.1	63	49	77.8	65.5	87.3
	Grade 3	62	4	6.5	1.8	15.7	58	3	5.2	1.1	14.4	63	0	0.0	0.0	5.7
Redness (mm)	All	62	5	8.1	2.7	17.8	58	7	12.1	5.0	23.3	63	7	11.1	4.6	21.6
	>100 mm	62	0	0.0	0.0	5.8	58	0	0.0	0.0	6.2	63	0	0.0	0.0	5.7
Swelling (mm)	All	62	6	9.7	3.6	19.9	58	7	12.1	5.0	23.3	63	4	6.3	1.8	15.5
	>100 mm	62	0	0.0	0.0	5.8	58	0	0.0	0.0	6.2	63	0	0.0	0.0	5.7
Dose 3																
Ecchymosis (mm)	All	-	-	-	-	-	-	-	-	-	-	55	0	0.0	0.0	6.5
	>100 mm	-	-	-	-	-	-	-	-	-	-	55	0	0.0	0.0	6.5
Induration (mm)	All	-	-	-	-	-	-	-	-	-	-	55	15	27.3	16.1	41.0
	>100 mm	-	-	-	-	-	-	-	-	-	-	55	0	0.0	0.0	6.5
Pain	All	-	-	-	-	-	-	-	-	-	-	55	48	87.3	75.5	94.7
	Grade 3	-	-	-	-	-	-	-	-	-	-	55	4	7.3	2.0	17.6
Redness (mm)	All	-	-	-	-	-	-	-	-	-	-	55	8	14.5	6.5	26.7
	>100 mm	-	-	-	-	-	-	-	-	-	-	55	0	0.0	0.0	6.5
Swelling (mm)	All	-	-	-	-	-	-	-	-	-	-	55	10	18.2	9.1	30.9
	>100 mm	-	-	-	-	-	-	-	-	-	-	55	0	0.0	0.0	6.5
Across doses																
Ecchymosis (mm)	All	64	0	0.0	0.0	5.6	64	2	3.1	0.4	10.8	65	4	6.2	1.7	15.0
	>100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5

Induration (mm)	All	64	14	21.9	12.5	34.0	64	16	25.0	15.0	37.4	65	24	36.9	25.3	49.8
	>100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
Pain	All	64	61	95.3	86.9	99.0	64	57	89.1	78.8	95.5	65	62	95.4	87.1	99.0
	Grade 3	64	8	12.5	5.6	23.2	64	8	12.5	5.6	23.2	65	5	7.7	2.5	17.0
Redness (mm)	All	64	8	12.5	5.6	23.2	64	11	17.2	8.9	28.7	65	13	20.0	11.1	31.8
	>100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
Swelling (mm)	All	64	10	15.6	7.8	26.9	64	13	20.3	11.3	32.2	65	16	24.6	14.8	36.9
	>100 mm	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5

Groups		**2VT/VT/12**				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Dose 1						
Ecchymosis (mm)	All	63	1	1.6	0.0	8.5
	>100 mm	63	0	0.0	0.0	5.7
Induration (mm)	All	63	8	12.7	5.6	23.5
	>100 mm	63	0	0.0	0.0	5.7
Pain	All	63	54	85.7	74.6	93.3
	Grade 3	63	1	1.6	0.0	8.5
Redness (mm)	All	63	5	7.9	2.6	17.6
	>100 mm	63	0	0.0	0.0	5.7
Swelling (mm)	All	63	9	14.3	6.7	25.4
	>100 mm	63	0	0.0	0.0	5.7
Dose 2						
Ecchymosis (mm)	All	60	0	0.0	0.0	6.0
	>100 mm	60	0	0.0	0.0	6.0
Induration (mm)	All	60	8	13.3	5.9	24.6
	>100 mm	60	0	0.0	0.0	6.0
Pain	All	60	47	78.3	65.8	87.9
	Grade 3	60	1	1.7	0.0	8.9
Redness (mm)	All	60	8	13.3	5.9	24.6
	>100 mm	60	1	1.7	0.0	8.9
Swelling (mm)	All	60	10	16.7	8.3	28.5
	>100 mm	60	0	0.0	0.0	6.0
Dose 3						
Ecchymosis (mm)	All	52	0	0.0	0.0	6.8
	>100 mm	52	0	0.0	0.0	6.8
Induration (mm)	All	52	10	19.2	9.6	32.5
	>100 mm	52	0	0.0	0.0	6.8
Pain	All	52	44	84.6	71.9	93.1
	Grade 3	52	4	7.7	2.1	18.5
Redness (mm)	All	52	8	15.4	6.9	28.1
	>100 mm	52	0	0.0	0.0	6.8
Swelling (mm)	All	52	8	15.4	6.9	28.1
	>100 mm	52	0	0.0	0.0	6.8
Across doses						
Ecchymosis (mm)	All	63	1	1.6	0.0	8.5
	>100 mm	63	0	0.0	0.0	5.7
Induration (mm)	All	63	19	30.2	19.2	43.0

	>100 mm	63	0	0.0	0.0	5.7
Pain	All	63	58	92.1	82.4	97.4
	Grade 3	63	5	7.9	2.6	17.6
Redness (mm)	All	63	15	23.8	14.0	36.2
	>100 mm	63	1	1.6	0.0	8.5
Swelling (mm)	All	63	16	25.4	15.3	37.9
	>100 mm	63	0	0.0	0.0	5.7

For each dose and across doses:
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
All: any symptom regardless of intensity
Grade 3 pain = pain that prevented normal activity

Primary Efficacy Results: Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total vaccinated cohort)

Groups		**VT/IN/6**					**VT/VT/6**					**2VT/IN/6**				
Symptom	**Type**	**N**	**n**	**%**	**95 % CI**		**N**	**n**	**%**	**95 % CI**		**N**	**n**	**%**	**95 % CI**	
					LL	**UL**				**LL**	**UL**				**LL**	**UL**
Dose 1																
Arthralgia	Any	62	8	12.9	5.7	23.9	66	12	18.2	9.8	29.6	64	11	17.2	8.9	28.7
	Grade 3	62	2	3.2	0.4	11.2	66	1	1.5	0.0	8.2	64	0	0.0	0.0	5.6
	Rel	62	7	11.3	4.7	21.9	66	12	18.2	9.8	29.6	64	9	14.1	6.6	25.0
Fatigue	Any	62	25	40.3	28.1	53.6	66	27	40.9	29.0	53.7	64	24	37.5	25.7	50.5
	Grade 3	62	0	0.0	0.0	5.8	66	1	1.5	0.0	8.2	64	2	3.1	0.4	10.8
	Rel	62	24	38.7	26.6	51.9	66	25	37.9	26.2	50.7	64	20	31.3	20.2	44.1
Fever/(Axillary) (°C)	>38.0	62	4	6.5	1.8	15.7	66	3	4.5	0.9	12.7	64	0	0.0	0.0	5.6
	>40.0	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
	Related	62	4	6.5	1.8	15.7	66	3	4.5	0.9	12.7	64	0	0.0	0.0	5.6
Headache	Any	62	22	35.5	23.7	48.7	66	18	27.3	17.0	39.6	64	19	29.7	18.9	42.4
	Grade 3	62	3	4.8	1.0	13.5	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
	Rel	62	21	33.9	22.3	47.0	66	15	22.7	13.3	34.7	64	18	28.1	17.6	40.8
Myalgia	Any	62	29	46.8	34.0	59.9	66	29	43.9	31.7	56.7	64	31	48.4	35.8	61.3
	Grade 3	62	3	4.8	1.0	13.5	66	1	1.5	0.0	8.2	64	0	0.0	0.0	5.6
	Rel	62	29	46.8	34.0	59.9	66	26	39.4	27.6	52.2	64	29	45.3	32.8	58.3
Shivering	Any	62	13	21.0	11.7	33.2	66	12	18.2	9.8	29.6	64	10	15.6	7.8	26.9
	Grade 3	62	3	4.8	1.0	13.5	66	1	1.5	0.0	8.2	64	0	0.0	0.0	5.6
	Rel	62	13	21.0	11.7	33.2	66	11	16.7	8.6	27.9	64	8	12.5	5.6	23.2
Sweating	Any	62	6	9.7	3.6	19.9	66	7	10.6	4.4	20.6	64	9	14.1	6.6	25.0
	Grade 3	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
	Rel	62	5	8.1	2.7	17.8	66	7	10.6	4.4	20.6	64	8	12.5	5.6	23.2
Dose 2																
Arthralgia	Any	57	12	21.1	11.4	33.9	57	20	35.1	22.9	48.9	64	11	17.2	8.9	28.7
	Grade 3	57	1	1.8	0.0	9.4	57	1	1.8	0.0	9.4	64	0	0.0	0.0	5.6
	Rel	57	12	21.1	11.4	33.9	57	16	28.1	17.0	41.5	64	9	14.1	6.6	25.0
Fatigue	Any	57	23	40.4	27.6	54.2	57	27	47.4	34.0	61.0	64	28	43.8	31.4	56.7
	Grade 3	57	2	3.5	0.4	12.1	57	1	1.8	0.0	9.4	64	0	0.0	0.0	5.6
	Rel	57	20	35.1	22.9	48.9	57	24	42.1	29.1	55.9	64	25	39.1	27.1	52.1
Fever/(Axillary (°C)	>38.0	57	2	3.5	0.4	12.1	57	2	3.5	0.4	12.1	64	1	1.6	0.0	8.4
	>40.0	57	0	0.0	0.0	6.3	57	0	0.0	0.0	6.3	64	0	0.0	0.0	5.6
	Related	57	2	3.5	0.4	12.1	57	2	3.5	0.4	12.1	64	1	1.6	0.0	8.4
Headache	Any	57	22	38.6	26.0	52.4	57	22	38.6	26.0	52.4	64	24	37.5	25.7	50.5
	Grade 3	57	1	1.8	0.0	9.4	57	2	3.5	0.4	12.1	64	0	0.0	0.0	5.6
	Rel	57	18	31.6	19.9	45.2	57	19	33.3	21.4	47.1	64	18	28.1	17.6	40.8
Myalgia	Any	57	28	49.1	35.6	62.7	57	32	56.1	42.4	69.3	64	27	42.2	29.9	55.2

	Grade 3	57	2	3.5	0.4	12.1	57	2	3.5	0.4	12.1	64	0	0.0	0.0	5.6
	Rel	57	25	43.9	30.7	57.6	57	27	47.4	34.0	61.0	64	23	35.9	24.3	48.9
Shivering	Any	57	14	24.6	14.1	37.8	57	21	36.8	24.4	50.7	64	10	15.6	7.8	26.9
	Grade 3	57	3	5.3	1.1	14.6	57	2	3.5	0.4	12.1	64	1	1.6	0.0	8.4
	Rel	57	12	21.1	11.4	33.9	57	19	33.3	21.4	47.1	64	9	14.1	6.6	25.0
Sweating	Any	57	10	17.5	8.7	29.9	57	12	21.1	11.4	33.9	64	12	18.8	10.1	30.5
	Grade 3	57	1	1.8	0.0	9.4	57	1	1.8	0.0	9.4	64	0	0.0	0.0	5.6
	Rel	57	8	14.0	6.3	25.8	57	9	15.8	7.5	27.9	64	12	18.8	10.1	30.5
Dose 3																
Arthralgia	Any	-	-	-	-	-	-	-	-	-	-	63	18	28.6	17.9	41.3
	Grade 3	-	-	-	-	-	-	-	-	-	-	63	0	0.0	0.0	5.7
	Rel	-	-	-	-	-	-	-	-	-	-	63	17	27.0	16.6	39.7
Fatigue	Any	-	-	-	-	-	-	-	-	-	-	63	32	50.8	37.9	63.6
	Grade 3	-	-	-	-	-	-	-	-	-	-	63	2	3.2	0.4	11.0
	Rel	-	-	-	-	-	-	-	-	-	-	63	28	44.4	31.9	57.5
Fever/(Axillary) (°C)	>38.0	-	-	-	-	-	-	-	-	-	-	63	3	4.8	1.0	13.3
	>40.0	-	-	-	-	-	-	-	-	-	-	63	0	0.0	0.0	5.7
	Related	-	-	-	-	-	-	-	-	-	-	63	2	3.2	0.4	11.0
Headache	Any	-	-	-	-	-	-	-	-	-	-	63	30	47.6	34.9	60.6
	Grade 3	-	-	-	-	-	-	-	-	-	-	63	1	1.6	0.0	8.5
	Rel	-	-	-	-	-	-	-	-	-	-	63	22	34.9	23.3	48.0
Myalgia	Any	-	-	-	-	-	-	-	-	-	-	63	35	55.6	42.5	68.1
	Grade 3	-	-	-	-	-	-	-	-	-	-	63	2	3.2	0.4	11.0
	Rel	-	-	-	-	-	-	-	-	-	-	63	31	49.2	36.4	62.1
Shivering	Any	-	-	-	-	-	-	-	-	-	-	63	17	27.0	16.6	39.7
	Grade 3	-	-	-	-	-	-	-	-	-	-	63	3	4.8	1.0	13.3
	Rel	-	-	-	-	-	-	-	-	-	-	63	15	23.8	14.0	36.2
Sweating	Any	-	-	-	-	-	-	-	-	-	-	63	13	20.6	11.5	32.7
	Grade 3	-	-	-	-	-	-	-	-	-	-	63	1	1.6	0.0	8.5
	Rel	-	-	-	-	-	-	-	-	-	-	63	11	17.5	9.1	29.1
Across doses																
Arthralgia	Any	62	17	27.4	16.9	40.2	66	25	37.9	26.2	50.7	64	27	42.2	29.9	55.2
	Grade 3	62	3	4.8	1.0	13.5	66	2	3.0	0.4	10.5	64	0	0.0	0.0	5.6
	Rel	62	16	25.8	15.5	38.5	66	22	33.3	22.2	46.0	64	26	40.6	28.5	53.6
Fatigue	Any	62	35	56.5	43.3	69.0	66	37	56.1	43.3	68.3	64	45	70.3	57.6	81.1
	Grade 3	62	2	3.2	0.4	11.2	66	2	3.0	0.4	10.5	64	3	4.7	1.0	13.1
	Rel	62	33	53.2	40.1	66.0	66	34	51.5	38.9	64.0	64	42	65.6	52.7	77.1
Fever/(Axillary) (°C)	>38.0	62	6	9.7	3.6	19.9	66	4	6.1	1.7	14.8	64	4	6.3	1.7	15.2
	>40.0	62	0	0.0	0.0	5.8	66	0	0.0	0.0	5.4	64	0	0.0	0.0	5.6
	Related	62	6	9.7	3.6	19.9	66	4	6.1	1.7	14.8	64	3	4.7	1.0	13.1
Headache	Any	62	34	54.8	41.7	67.5	66	31	47.0	34.6	59.7	64	41	64.1	51.1	75.7
	Grade 3	62	4	6.5	1.8	15.7	66	2	3.0	0.4	10.5	64	1	1.6	0.0	8.4
	Rel	62	31	50.0	37.0	63.0	66	28	42.4	30.3	55.2	64	36	56.3	43.3	68.6
Myalgia	Any	62	41	66.1	53.0	77.7	66	41	62.1	49.3	73.8	64	47	73.4	60.9	83.7
	Grade 3	62	5	8.1	2.7	17.8	66	3	4.5	0.9	12.7	64	2	3.1	0.4	10.8
	Rel	62	39	62.9	49.7	74.8	66	38	57.6	44.8	69.7	64	46	71.9	59.2	82.4
Shivering	Any	62	22	35.5	23.7	48.7	66	28	42.4	30.3	55.2	64	24	37.5	25.7	50.5
	Grade 3	62	6	9.7	3.6	19.9	66	3	4.5	0.9	12.7	64	3	4.7	1.0	13.1
	Rel	62	21	33.9	22.3	47.0	66	26	39.4	27.6	52.2	64	21	32.8	21.6	45.7
Sweating	Any	62	15	24.2	14.2	36.7	66	18	27.3	17.0	39.6	64	23	35.9	24.3	48.9
	Grade 3	62	1	1.6	0.0	8.7	66	1	1.5	0.0	8.2	64	1	1.6	0.0	8.4
	Rel	62	13	21.0	11.7	33.2	66	15	22.7	13.3	34.7	64	21	32.8	21.6	45.7

Groups		**2VT/VT/6**			
Symptom	**Type**	**N**	**n**	**%**	**95 % CI**

					LL	UL
Dose 1						
Arthralgia	Any	62	15	24.2	14.2	36.7
	Grade 3	62	0	0.0	0.0	5.8
	Rel	62	12	19.4	10.4	31.4
Fatigue	Any	62	26	41.9	29.5	55.2
	Grade 3	62	0	0.0	0.0	5.8
	Rel	62	20	32.3	20.9	45.3
Fever/(Axillary) (°C)	>38.0	62	1	1.6	0.0	8.7
	>40.0	62	0	0.0	0.0	5.8
	Related	62	0	0.0	0.0	5.8
Headache	Any	62	25	40.3	28.1	53.6
	Grade 3	62	4	6.5	1.8	15.7
	Rel	62	21	33.9	22.3	47.0
Myalgia	Any	62	32	51.6	38.6	64.5
	Grade 3	62	0	0.0	0.0	5.8
	Rel	62	30	48.4	35.5	61.4
Shivering	Any	62	21	33.9	22.3	47.0
	Grade 3	62	0	0.0	0.0	5.8
	Rel	62	19	30.6	19.6	43.7
Sweating	Any	62	12	19.4	10.4	31.4
	Grade 3	62	1	1.6	0.0	8.7
	Rel	62	10	16.1	8.0	27.7
Dose 2						
Arthralgia	Any	61	13	21.3	11.9	33.7
	Grade 3	61	1	1.6	0.0	8.8
	Rel	61	12	19.7	10.6	31.8
Fatigue	Any	61	21	34.4	22.7	47.7
	Grade 3	61	0	0.0	0.0	5.9
	Rel	61	19	31.1	19.9	44.3
Fever/(Axillary) (°C)	>38.0	61	0	0.0	0.0	5.9
	>40.0	61	0	0.0	0.0	5.9
	Related	61	0	0.0	0.0	5.9
Headache	Any	61	26	42.6	30.0	55.9
	Grade 3	61	3	4.9	1.0	13.7
	Rel	61	22	36.1	24.2	49.4
Myalgia	Any	61	22	36.1	24.2	49.4
	Grade 3	61	1	1.6	0.0	8.8
	Rel	61	21	34.4	22.7	47.7
Shivering	Any	61	13	21.3	11.9	33.7
	Grade 3	61	1	1.6	0.0	8.8
	Rel	61	13	21.3	11.9	33.7
Sweating	Any	61	5	8.2	2.7	18.1
	Grade 3	61	0	0.0	0.0	5.9
	Rel	61	4	6.6	1.8	15.9
Dose 3						
Arthralgia	Any	58	19	32.8	21.0	46.3
	Grade 3	58	3	5.2	1.1	14.4
	Rel	58	16	27.6	16.7	40.9
Fatigue	Any	58	30	51.7	38.2	65.0
	Grade 3	58	3	5.2	1.1	14.4
	Rel	58	27	46.6	33.3	60.1
Fever/(Axillary) (°C)	>38.0	58	3	5.2	1.1	14.4
	>40.0	58	0	0.0	0.0	6.2

	Related	58	3	5.2	1.1	14.4
Headache	Any	58	28	48.3	35.0	61.8
	Grade 3	58	4	6.9	1.9	16.7
	Rel	58	26	44.8	31.7	58.5
Myalgia	Any	58	36	62.1	48.4	74.5
	Grade 3	58	3	5.2	1.1	14.4
	Rel	58	33	56.9	43.2	69.8
Shivering	Any	58	19	32.8	21.0	46.3
	Grade 3	58	4	6.9	1.9	16.7
	Rel	58	17	29.3	18.1	42.7
Sweating	Any	58	13	22.4	12.5	35.3
	Grade 3	58	2	3.4	0.4	11.9
	Rel	58	12	20.7	11.2	33.4
Across doses						
Arthralgia	Any	62	28	45.2	32.5	58.3
	Grade 3	62	4	6.5	1.8	15.7
	Rel	62	25	40.3	28.1	53.6
Fatigue	Any	62	44	71.0	58.1	81.8
	Grade 3	62	3	4.8	1.0	13.5
	Rel	62	38	61.3	48.1	73.4
Fever/(Axillary) (°C)	>38.0	62	4	6.5	1.8	15.7
	>40.0	62	0	0.0	0.0	5.8
	Related	62	3	4.8	1.0	13.5
Headache	Any	62	41	66.1	53.0	77.7
	Grade 3	62	8	12.9	5.7	23.9
	Rel	62	38	61.3	48.1	73.4
Myalgia	Any	62	48	77.4	65.0	87.1
	Grade 3	62	4	6.5	1.8	15.7
	Rel	62	47	75.8	63.3	85.8
Shivering	Any	62	36	58.1	44.8	70.5
	Grade 3	62	5	8.1	2.7	17.8
	Rel	62	34	54.8	41.7	67.5
Sweating	Any	62	20	32.3	20.9	45.3
	Grade 3	62	3	4.8	1.0	13.5
	Rel	62	17	27.4	16.9	40.2

For each dose and across doses:
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= any symptom regardless of the intensity and the relationship to study vaccination
Grade 3 = symptoms that prevented normal activity
Rel = symptoms assessed by the investigator to be casually related to vaccination

Primary Efficacy Results: Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall – for subjects boosted at month 12 (Total vaccinated cohort)

Groups		**VT/IN/12**					**VT/VT/12**					**2VT/IN/12**				
Symptom	**Type**	**N**	**n**	**%**	**95 % CI**		**N**	**n**	**%**	**95 % CI**		**N**	**n**	**%**	**95 % CI**	
					LL	**UL**				**LL**	**UL**				**LL**	**UL**
Dose 1																
Arthralgia	All	64	13	20.3	11.3	32.2	64	9	14.1	6.6	25.0	65	8	12.3	5.5	22.8
	Grade 3	64	2	3.1	0.4	10.8	64	0	0.0	0.0	5.6	65	1	1.5	0.0	8.3
	Related	64	13	20.3	11.3	32.2	64	8	12.5	5.6	23.2	65	6	9.2	3.5	19.0
Fatigue	All	64	27	42.2	29.9	55.2	64	21	32.8	21.6	45.7	65	25	38.5	26.7	51.4
	Grade 3	64	0	0.0	0.0	5.6	64	1	1.6	0.0	8.4	65	0	0.0	0.0	5.5
	Related	64	27	42.2	29.9	55.2	64	19	29.7	18.9	42.4	65	19	29.2	18.6	41.8

Fever/(Axillary) (°C)	>38.0	64	0	0.0	0.0	5.6	64	1	1.6	0.0	8.4	65	1	1.5	0.0	8.3
	>40.0	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
	Related	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	1	1.5	0.0	8.3
Headache	All	64	18	28.1	17.6	40.8	64	24	37.5	25.7	50.5	65	28	43.1	30.8	56.0
	Grade 3	64	0	0.0	0.0	5.6	64	1	1.6	0.0	8.4	65	0	0.0	0.0	5.5
	Related	64	17	26.6	16.3	39.1	64	21	32.8	21.6	45.7	65	23	35.4	23.9	48.2
Myalgia	All	64	31	48.4	35.8	61.3	64	29	45.3	32.8	58.3	65	27	41.5	29.4	54.4
	Grade 3	64	2	3.1	0.4	10.8	64	1	1.6	0.0	8.4	65	2	3.1	0.4	10.7
	Related	64	30	46.9	34.3	59.8	64	27	42.2	29.9	55.2	65	26	40.0	28.0	52.9
Shivering	All	64	15	23.4	13.8	35.7	64	8	12.5	5.6	23.2	65	9	13.8	6.5	24.7
	Grade 3	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
	Related	64	14	21.9	12.5	34.0	64	8	12.5	5.6	23.2	65	6	9.2	3.5	19.0
Sweating	All	64	5	7.8	2.6	17.3	64	2	3.1	0.4	10.8	65	5	7.7	2.5	17.0
	Grade 3	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
	Related	64	5	7.8	2.6	17.3	64	1	1.6	0.0	8.4	65	4	6.2	1.7	15.0
Dose 2																
Arthralgia	All	62	14	22.6	12.9	35.0	58	12	20.7	11.2	33.4	63	15	23.8	14.0	36.2
	Grade 3	62	1	1.6	0.0	8.7	58	1	1.7	0.0	9.2	63	3	4.8	1.0	13.3
	Related	62	14	22.6	12.9	35.0	58	11	19.0	9.9	31.4	63	13	20.6	11.5	32.7
Fatigue	All	62	30	48.4	35.5	61.4	58	22	37.9	25.5	51.6	63	21	33.3	22.0	46.3
	Grade 3	62	5	8.1	2.7	17.8	58	3	5.2	1.1	14.4	63	4	6.3	1.8	15.5
	Related	62	28	45.2	32.5	58.3	58	22	37.9	25.5	51.6	63	18	28.6	17.9	41.3
Fever/(Axillary) (°C)	>38.0	62	4	6.5	1.8	15.7	58	3	5.2	1.1	14.4	63	1	1.6	0.0	8.5
	>40.0	62	0	0.0	0.0	5.8	58	0	0.0	0.0	6.2	63	0	0.0	0.0	5.7
	Related	62	4	6.5	1.8	15.7	58	2	3.4	0.4	11.9	63	1	1.6	0.0	8.5
Headache	All	62	24	38.7	26.6	51.9	58	22	37.9	25.5	51.6	63	20	31.7	20.6	44.7
	Grade 3	62	1	1.6	0.0	8.7	58	2	3.4	0.4	11.9	63	1	1.6	0.0	8.5
	Related	62	23	37.1	25.2	50.3	58	20	34.5	22.5	48.1	63	16	25.4	15.3	37.9
Myalgia	All	62	40	64.5	51.3	76.3	58	30	51.7	38.2	65.0	63	29	46.0	33.4	59.1
	Grade 3	62	3	4.8	1.0	13.5	58	2	3.4	0.4	11.9	63	3	4.8	1.0	13.3
	Related	62	37	59.7	46.4	71.9	58	26	44.8	31.7	58.5	63	28	44.4	31.9	57.5
Shivering	All	62	17	27.4	16.9	40.2	58	14	24.1	13.9	37.2	63	9	14.3	6.7	25.4
	Grade 3	62	4	6.5	1.8	15.7	58	2	3.4	0.4	11.9	63	2	3.2	0.4	11.0
	Related	62	17	27.4	16.9	40.2	58	14	24.1	13.9	37.2	63	8	12.7	5.6	23.5
Sweating	All	62	13	21.0	11.7	33.2	58	6	10.3	3.9	21.2	63	12	19.0	10.2	30.9
	Grade 3	62	1	1.6	0.0	8.7	58	1	1.7	0.0	9.2	63	2	3.2	0.4	11.0
	Related	62	12	19.4	10.4	31.4	58	6	10.3	3.9	21.2	63	10	15.9	7.9	27.3
Dose 3																
Arthralgia	All	-	-	-	-	-	-	-	-	-	-	55	19	34.5	22.2	48.6
	Grade 3	-	-	-	-	-	-	-	-	-	-	55	4	7.3	2.0	17.6
	Related	-	-	-	-	-	-	-	-	-	-	55	17	30.9	19.1	44.8
Fatigue	All	-	-	-	-	-	-	-	-	-	-	55	29	52.7	38.8	66.3
	Grade 3	-	-	-	-	-	-	-	-	-	-	55	0	0.0	0.0	6.5
	Related	-	-	-	-	-	-	-	-	-	-	55	24	43.6	30.3	57.7
Fever/(Axillary) (°C)	>38.0	-	-	-	-	-	-	-	-	-	-	55	3	5.5	1.1	15.1
	>40.0	-	-	-	-	-	-	-	-	-	-	55	0	0.0	0.0	6.5
	Related	-	-	-	-	-	-	-	-	-	-	55	3	5.5	1.1	15.1
Headache	All	-	-	-	-	-	-	-	-	-	-	55	23	41.8	28.7	55.9
	Grade 3	-	-	-	-	-	-	-	-	-	-	55	1	1.8	0.0	9.7
	Related	-	-	-	-	-	-	-	-	-	-	55	20	36.4	23.8	50.4
Myalgia	All	-	-	-	-	-	-	-	-	-	-	55	31	56.4	42.3	69.7
	Grade 3	-	-	-	-	-	-	-	-	-	-	55	4	7.3	2.0	17.6
	Related	-	-	-	-	-	-	-	-	-	-	55	28	50.9	37.1	64.6
Shivering	All	-	-	-	-	-	-	-	-	-	-	55	18	32.7	20.7	46.7

	Grade 3	-	-	-	-	-	-	-	-	-	-	55	2	3.6	0.4	12.5
	Related	-	-	-	-	-	-	-	-	-	-	55	17	30.9	19.1	44.8
Sweating	All	-	-	-	-	-	-	-	-	-	-	55	11	20.0	10.4	33.0
	Grade 3	-	-	-	-	-	-	-	-	-	-	55	1	1.8	0.0	9.7
	Related	-	-	-	-	-	-	-	-	-	-	55	10	18.2	9.1	30.9
Across doses																
Arthralgia	All	64	20	31.3	20.2	44.1	64	13	20.3	11.3	32.2	65	29	44.6	32.3	57.5
	Grade 3	64	3	4.7	1.0	13.1	64	1	1.6	0.0	8.4	65	5	7.7	2.5	17.0
	Related	64	20	31.3	20.2	44.1	64	12	18.8	10.1	30.5	65	25	38.5	26.7	51.4
Fatigue	All	64	37	57.8	44.8	70.1	64	33	51.6	38.7	64.2	65	47	72.3	59.8	82.7
	Grade 3	64	5	7.8	2.6	17.3	64	4	6.3	1.7	15.2	65	4	6.2	1.7	15.0
	Related	64	36	56.3	43.3	68.6	64	31	48.4	35.8	61.3	65	40	61.5	48.6	73.3
Fever/(Axillary) (°C)	>38.0	64	4	6.3	1.7	15.2	64	4	6.3	1.7	15.2	65	4	6.2	1.7	15.0
	>40.0	64	0	0.0	0.0	5.6	64	0	0.0	0.0	5.6	65	0	0.0	0.0	5.5
	Related	64	4	6.3	1.7	15.2	64	2	3.1	0.4	10.8	65	4	6.2	1.7	15.0
Headache	All	64	31	48.4	35.8	61.3	64	34	53.1	40.2	65.7	65	45	69.2	56.6	80.1
	Grade 3	64	1	1.6	0.0	8.4	64	3	4.7	1.0	13.1	65	2	3.1	0.4	10.7
	Related	64	30	46.9	34.3	59.8	64	30	46.9	34.3	59.8	65	41	63.1	50.2	74.7
Myalgia	All	64	49	76.6	64.3	86.2	64	41	64.1	51.1	75.7	65	45	69.2	56.6	80.1
	Grade 3	64	4	6.3	1.7	15.2	64	3	4.7	1.0	13.1	65	7	10.8	4.4	20.9
	Related	64	45	70.3	57.6	81.1	64	39	60.9	47.9	72.9	65	43	66.2	53.4	77.4
Shivering	All	64	22	34.4	22.9	47.3	64	19	29.7	18.9	42.4	65	25	38.5	26.7	51.4
	Grade 3	64	4	6.3	1.7	15.2	64	2	3.1	0.4	10.8	65	4	6.2	1.7	15.0
	Related	64	22	34.4	22.9	47.3	64	19	29.7	18.9	42.4	65	23	35.4	23.9	48.2
Sweating	All	64	16	25.0	15.0	37.4	64	7	10.9	4.5	21.2	65	23	35.4	23.9	48.2
	Grade 3	64	1	1.6	0.0	8.4	64	1	1.6	0.0	8.4	65	3	4.6	1.0	12.9
	Related	64	15	23.4	13.8	35.7	64	6	9.4	3.5	19.3	65	21	32.3	21.2	45.1

Groups		**2VT/VT/12**				
Symptom	**Type**	**N**	**n**	**%**	**95 % CI**	
					LL	**UL**
Dose 1						
Arthralgia	All	63	6	9.5	3.6	19.6
	Grade 3	63	0	0.0	0.0	5.7
	Related	63	6	9.5	3.6	19.6
Fatigue	All	63	25	39.7	27.6	52.8
	Grade 3	63	0	0.0	0.0	5.7
	Related	63	23	36.5	24.7	49.6
Fever/(Axillary) (°C)	>38.0	63	2	3.2	0.4	11.0
	>40.0	63	0	0.0	0.0	5.7
	Related	63	2	3.2	0.4	11.0
Headache	All	63	20	31.7	20.6	44.7
	Grade 3	63	1	1.6	0.0	8.5
	Related	63	19	30.2	19.2	43.0
Myalgia	All	63	31	49.2	36.4	62.1
	Grade 3	63	0	0.0	0.0	5.7
	Related	63	29	46.0	33.4	59.1
Shivering	All	63	14	22.2	12.7	34.5
	Grade 3	63	1	1.6	0.0	8.5
	Related	63	13	20.6	11.5	32.7
Sweating	All	63	12	19.0	10.2	30.9
	Grade 3	63	1	1.6	0.0	8.5
	Related	63	12	19.0	10.2	30.9
Dose 2						
Arthralgia	All	60	15	25.0	14.7	37.9

	Grade 3	60	1	1.7	0.0	8.9
	Related	60	14	23.3	13.4	36.0
Fatigue	All	60	27	45.0	32.1	58.4
	Grade 3	60	0	0.0	0.0	6.0
	Related	60	26	43.3	30.6	56.8
Fever/(Axillary) (°C)	>38.0	60	2	3.3	0.4	11.5
	>40.0	60	0	0.0	0.0	6.0
	Related	60	2	3.3	0.4	11.5
Headache	All	60	15	25.0	14.7	37.9
	Grade 3	60	0	0.0	0.0	6.0
	Related	60	13	21.7	12.1	34.2
Myalgia	All	60	28	46.7	33.7	60.0
	Grade 3	60	2	3.3	0.4	11.5
	Related	60	25	41.7	29.1	55.1
Shivering	All	60	14	23.3	13.4	36.0
	Grade 3	60	0	0.0	0.0	6.0
	Related	60	14	23.3	13.4	36.0
Sweating	All	60	7	11.7	4.8	22.6
	Grade 3	60	0	0.0	0.0	6.0
	Related	60	6	10.0	3.8	20.5
Dose 3						
Arthralgia	All	52	14	26.9	15.6	41.0
	Grade 3	52	1	1.9	0.0	10.3
	Related	52	13	25.0	14.0	38.9
Fatigue	All	52	29	55.8	41.3	69.5
	Grade 3	52	2	3.8	0.5	13.2
	Related	52	28	53.8	39.5	67.8
Fever/(Axillary) (°C)	>38.0	52	2	3.8	0.5	13.2
	>40.0	52	0	0.0	0.0	6.8
	Related	52	2	3.8	0.5	13.2
Headache	All	52	32	61.5	47.0	74.7
	Grade 3	52	2	3.8	0.5	13.2
	Related	52	25	48.1	34.0	62.4
Myalgia	All	52	29	55.8	41.3	69.5
	Grade 3	52	2	3.8	0.5	13.2
	Related	52	27	51.9	37.6	66.0
Shivering	All	52	21	40.4	27.0	54.9
	Grade 3	52	3	5.8	1.2	15.9
	Related	52	21	40.4	27.0	54.9
Sweating	All	52	15	28.8	17.1	43.1
	Grade 3	52	0	0.0	0.0	6.8
	Related	52	13	25.0	14.0	38.9
Across doses						
Arthralgia	All	63	26	41.3	29.0	54.4
	Grade 3	63	2	3.2	0.4	11.0
	Related	63	24	38.1	26.1	51.2
Fatigue	All	63	44	69.8	57.0	80.8
	Grade 3	63	2	3.2	0.4	11.0
	Related	63	42	66.7	53.7	78.0
Fever/(Axillary)	>38.0	63	5	7.9	2.6	17.6
(°C)	>40.0	63	0	0.0	0.0	5.7
	Related	63	5	7.9	2.6	17.6
Headache	All	63	41	65.1	52.0	76.7
	Grade 3	63	3	4.8	1.0	13.3

	Related	63	35	55.6	42.5	68.1
Myalgia	All	63	47	74.6	62.1	84.7
	Grade 3	63	4	6.3	1.8	15.5
	Related	63	43	68.3	55.3	79.4
Shivering	All	63	29	46.0	33.4	59.1
	Grade 3	63	4	6.3	1.8	15.5
	Related	63	29	46.0	33.4	59.1
Sweating	All	63	25	39.7	27.6	52.8
	Grade 3	63	1	1.6	0.0	8.5
	Related	63	24	38.1	26.1	51.2

For each dose and across doses:
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= any symptom regardless of the intensity and the relationship to study vaccination
Grade 3 = symptoms that prevented normal activity
Rel = symptoms assessed by the investigator to be casually related to vaccination

Primary Efficacy Results: Percentage, intensity and relationship to vaccination of unsolicited local and general signs and symptoms during a 30-day follow-up period after primary vaccination(s) and booster vaccination, and overall.
Please refer to the safety section at the end of the document.

Primary Efficacy Results: Occurrence of serious adverse events (SAEs) during the entire study
Please refer to the safety section at the end of the document.

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 6 for adults who received booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	≥ 1:10				GMT		
				n	%	95%CI		value	95%CI	
						LL	UL		LL	UL
A/Indonesia	VT/IN/12	PRE	59	0	0.0	0.0	6.1	5.0	5.0	5.0
		PI(D21)	58	9	15.5	7.3	27.4	6.8	5.5	8.3
		PI(M6)	59	6	10.2	3.8	20.8	5.7	5.1	6.4
	VT/VT/12	PRE	60	0	0.0	0.0	6.0	5.0	5.0	5.0
		PI(D21)	60	8	13.3	5.9	24.6	6.3	5.2	7.7
		PI(M6)	57	2	3.5	0.4	12.1	5.4	4.8	6.0
	2VT/IN/12	PRE	55	0	0.0	0.0	6.5	5.0	5.0	5.0
		PI(D21)	55	7	12.7	5.3	24.5	6.0	5.2	6.8
		PII(D42)	49	34	69.4	54.6	81.7	28.0	18.0	43.6
		PII(M6)	52	24	46.2	32.2	60.5	10.2	7.8	13.3
	2VT/VT/12	PRE	55	0	0.0	0.0	6.5	5.0	5.0	5.0
		PI(D21)	55	4	7.3	2.0	17.6	5.3	5.0	5.7
		PII(D42)	48	27	56.3	41.2	70.5	18.6	12.7	27.2
		PII(M6)	51	12	23.5	12.8	37.5	6.5	5.6	7.5
A/Vietnam	VT/IN/12	PRE	59	0	0.0	0.0	6.1	5.0	5.0	5.0
		PI(D21)	58	31	53.4	39.9	66.7	22.1	14.5	33.8
		PI(M6)	59	25	42.4	29.6	55.9	13.2	9.3	18.7
	VT/VT/12	PRE	60	1	1.7	0.0	8.9	5.1	4.9	5.4
		PI(D21)	60	31	51.7	38.4	64.8	17.6	12.3	25.2
		PI(M6)	57	24	42.1	29.1	55.9	10.6	8.0	14.0
	2VT/IN/12	PRE	55	1	1.8	0.0	9.7	5.1	4.9	5.4
		PI(D21)	55	31	56.4	42.3	69.7	21.4	14.3	32.0
		PII(D42)	49	46	93.9	83.1	98.7	239.4	157.2	364.8
		PII(M6)	52	41	78.8	65.3	88.9	38.4	26.6	55.5
	2VT/VT/12	PRE	55	1	1.8	0.0	9.7	5.2	4.8	5.5
		PI(D21)	55	27	49.1	35.4	62.9	15.8	10.9	23.1

		PII(D42)	48	43	89.6	77.3	96.5	178.3	116.6	272.5
		PII(M6)	51	36	70.6	56.2	82.5	24.0	17.2	33.5

GMT = Geometric Mean antibody Titer
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:10)
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6

Secondary Outcome Variable(s): SCR of H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 6 for adults who received booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCR			
				n	%	95%CI	
						LL	UL
A/Indonesia	VT/IN/12	PI(D21)	58	5	8.6	2.9	19.0
		PI(M6)	59	0	0.0	0.0	6.1
	VT/VT/12	PI(D21)	60	3	5.0	1.0	13.9
		PI(M6)	57	1	1.8	0.0	9.4
	2VT/IN/12	PI(D21)	55	1	1.8	0.0	9.7
		PII(D42)	49	24	49.0	34.4	63.7
		PII(M6)	52	7	13.5	5.6	25.8
	2VT/VT/12	PI(D21)	55	0	0.0	0.0	6.5
		PII(D42)	48	20	41.7	27.6	56.8
		PII(M6)	51	1	2.0	0.0	10.4
A/Vietnam	VT/IN/12	PI(D21)	58	26	44.8	31.7	58.5
		PI(M6)	59	15	25.4	15.0	38.4
	VT/VT/12	PI(D21)	60	24	40.0	27.6	53.5
		PI(M6)	57	10	17.5	8.7	29.9
	2VT/IN/12	PI(D21)	55	25	45.5	32.0	59.4
		PII(D42)	49	44	89.8	77.8	96.6
		PII(M6)	52	35	67.3	52.9	79.7
	2VT/VT/12	PI(D21)	55	16	29.1	17.6	42.9
		PII(D42)	48	43	89.6	77.3	96.5
		PII(M6)	51	24	47.1	32.9	61.5

Seroconversion defined as:
For initially seronegative subjects (at day 0), antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects (at day 0), antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6

Secondary Outcome Variable(s): SCF of H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 6 for adults who received booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCF		
				Value	95%CI	
					LL	UL
A/Indonesia	VT/IN/12	PI(M6)	59	1.1	1.0	1.3
	VT/VT/12	PI(M6)	57	1.1	1.0	1.2
	2VT/IN/12	PII(M6)	52	2.0	1.6	2.7
	2VT/VT/12	PII(M6)	51	1.3	1.1	1.5

A/Vietnam	VT/IN/12	PI(M6)	59	2.6	1.9	3.7
	VT/VT/12	PI(M6)	57	2.1	1.6	2.7
	2VT/IN/12	PII(M6)	52	7.5	5.2	10.8
	2VT/VT/12	PII(M6)	51	4.6	3.4	6.4

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/D0)])
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M6) = Post-vaccination dose 1 at Month 6
PII(M6) = Post-vaccination dose 2 at Month 6

Secondary Outcome Variable(s): SPR of H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 6 for adults who received booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SPR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Indonesia	VT/IN/12	PRE	59	0	0.0	0.0	6.1
		PI(D21)	58	5	8.6	2.9	19.0
		PI(M6)	59	0	0.0	0.0	6.1
	VT/VT/12	PRE	60	0	0.0	0.0	6.0
		PI(D21)	60	3	5.0	1.0	13.9
		PI(M6)	57	1	1.8	0.0	9.4
	2VT/IN/12	PRE	55	0	0.0	0.0	6.5
		PI(D21)	55	1	1.8	0.0	9.7
		PII(D42)	49	24	49.0	34.4	63.7
		PII(M6)	52	7	13.5	5.6	25.8
	2VT/VT/12	PRE	55	0	0.0	0.0	6.5
		PI(D21)	55	0	0.0	0.0	6.5
		PII(D42)	48	20	41.7	27.6	56.8
		PII(M6)	51	1	2.0	0.0	10.4
A/Vietnam	VT/IN/12	PRE	59	0	0.0	0.0	6.1
		PI(D21)	58	26	44.8	31.7	58.5
		PI(M6)	59	15	25.4	15.0	38.4
	VT/VT/12	PRE	60	0	0.0	0.0	6.0
		PI(D21)	60	24	40.0	27.6	53.5
		PI(M6)	57	10	17.5	8.7	29.9
	2VT/IN/12	PRE	55	0	0.0	0.0	6.5
		PI(D21)	55	25	45.5	32.0	59.4
		PII(D42)	49	45	91.8	80.4	97.7
		PII(M6)	52	36	69.2	54.9	81.3
	2VT/VT/12	PRE	55	0	0.0	0.0	6.5
		PI(D21)	55	17	30.9	19.1	44.8
		PII(D42)	48	43	89.6	77.3	96.5
		PII(M6)	51	24	47.1	32.9	61.5

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6

Secondary Outcome Variable(s): Seropositivity rates and GMTs for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:10**			**GMT**	
				n	**%**	**95%CI**	**value**	**95%CI**

						LL	UL		LL	UL
A/Vietnam	VT/VT/6	PRE	50	1	2.0	0.1	10.6	5.2	4.8	5.5
		PI(D21)	50	25	50.0	35.5	64.5	16.1	11.2	23.3
		PI(M6)	45	17	37.8	23.8	53.5	9.8	7.4	12.9
		PII(M6+D7)	43	39	90.7	77.9	97.4	224.5	144.0	349.9
		PII(M6+D21)	44	40	90.9	78.3	97.5	327.7	205.3	523.0
		PII(M12)	43	35	81.4	66.6	91.6	63.8	40.6	100.3
	VT/IN/6	PRE	53	0	0.0	0.0	6.7	5.0	5.0	5.0
		PI(D21)	53	30	56.6	42.3	70.2	21.3	14.3	31.9
		PI(M6)	52	24	46.2	32.2	60.5	11.8	8.8	15.8
		PII(M6+D7)	50	49	98.0	89.4	99.9	211.2	156.2	285.5
		PII(M6+D21)	49	48	98.0	89.1	99.9	404.1	290.2	562.6
		PII(M12)	47	40	85.1	71.7	93.8	62.7	41.1	95.7
	2VT/VT/6	PRE	45	2	4.4	0.5	15.1	5.8	4.7	7.1
		PI(D21)	45	28	62.2	46.5	76.2	31.5	18.8	52.8
		PII(D42)	39	37	94.9	82.7	99.4	275.1	178.2	424.7
		PII(M6)	45	31	68.9	53.4	81.8	31.7	20.7	48.7
		PIII(M6+D7)	43	39	90.7	77.9	97.4	215.5	136.8	339.6
		PIII(M6+D21)	43	40	93.0	80.9	98.5	358.2	222.2	577.4
		PIII(M12)	43	38	88.4	74.9	96.1	101.8	63.3	163.8
	2VT/IN/6	PRE	49	1	2.0	0.1	10.9	5.2	4.8	5.7
		PI(D21)	49	32	65.3	50.4	78.3	33.5	21.1	53.2
		PII(D42)	43	40	93.0	80.9	98.5	226.2	149.9	341.5
		PII(M6)	48	34	70.8	55.9	83.0	28.9	19.4	43.0
		PIII(M6+D7)	47	43	91.5	79.6	97.6	195.2	122.1	312.0
		PIII(M6+D21)	48	46	95.8	85.7	99.5	553.8	353.3	868.3
		PIII(M12)	46	40	87.0	73.7	95.1	108.9	68.1	174.0
A/Indonesia	VT/VT/6	PRE	50	0	0.0	0.0	7.1	5.0	5.0	5.0
		PI(D21)	50	7	14.0	5.8	26.7	5.6	5.2	6.1
		PI(M6)	45	2	4.4	0.5	15.1	5.3	4.9	5.7
		PII(M6+D7)	43	34	79.1	64.0	90.0	68.1	42.3	109.5
		PII(M6+D21)	44	38	86.4	72.6	94.8	101.3	65.9	155.8
		PII(M12)	43	25	58.1	42.1	73.0	17.6	11.8	26.2
	VT/IN/6	PRE	53	0	0.0	0.0	6.7	5.0	5.0	5.0
		PI(D21)	53	8	15.1	6.7	27.6	6.4	5.4	7.6
		PI(M6)	52	4	7.7	2.1	18.5	5.5	5.0	6.0
		PII(M6+D7)	50	49	98.0	89.4	99.9	142.3	103.7	195.0
		PII(M6+D21)	49	48	98.0	89.1	99.9	281.7	198.3	400.3
		PII(M12)	47	35	74.5	59.7	86.1	40.6	26.0	63.3
	2VT/VT/6	PRE	45	0	0.0	0.0	7.9	5.0	5.0	5.0
		PI(D21)	45	4	8.9	2.5	21.2	5.4	5.0	5.7
		PII(D42)	39	20	51.3	34.8	67.6	16.7	10.8	25.8
		PII(M6)	45	11	24.4	12.9	39.5	6.9	5.7	8.3
		PIII(M6+D7)	43	35	81.4	66.6	91.6	61.3	39.3	95.7
		PIII(M6+D21)	43	38	88.4	74.9	96.1	121.7	78.2	189.3
		PIII(M12)	43	25	58.1	42.1	73.0	24.3	15.0	39.3
	2VT/IN/6	PRE	49	0	0.0	0.0	7.3	5.0	5.0	5.0
		PI(D21)	49	6	12.2	4.6	24.8	6.2	5.2	7.5
		PII(D42)	43	26	60.5	44.4	75.0	22.9	15.1	34.9
		PII(M6)	48	17	35.4	22.2	50.5	8.3	6.4	10.8
		PIII(M6+D7)	47	41	87.2	74.3	95.2	127.3	78.7	205.9
		PIII(M6+D21)	48	46	95.8	85.7	99.5	380.6	247.6	585.1
		PIII(M12)	46	34	73.9	58.9	85.7	57.9	34.8	96.2

GMT = geometric mean antibody titer calculated on all subjects

N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95%CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12))= Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): Seropositivity rates and GMTs for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12 + 21 Days, for adults who received the booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	≥ 1:10				GMT		
				n	%	95%CI		value	95%CI	
						LL	UL		LL	UL
A/Vietnam	VT/VT/12	PRE	55	1	1.8	0.0	9.7	5.1	4.9	5.4
		PI(D21)	55	29	52.7	38.8	66.3	18.4	12.6	27.0
		PI(M6)	53	21	39.6	26.5	54.0	10.2	7.6	13.6
		PI(M12)	52	15	28.8	17.1	43.1	8.4	6.4	11.0
		PII(M12+D7)	50	46	92.0	80.8	97.8	235.9	153.7	362.1
		PII(M12+D21)	50	47	94.0	83.5	98.7	352.6	229.9	540.8
	VT/IN/12	PRE	53	0	0.0	0.0	6.7	5.0	5.0	5.0
		PI(D21)	53	27	50.9	36.8	64.9	20.3	13.1	31.5
		PI(M6)	53	22	41.5	28.1	55.9	12.6	8.9	17.8
		PI(M12)	52	18	34.6	22.0	49.1	9.9	7.3	13.5
		PII(M12+D7)	51	50	98.0	89.6	100	354.3	244.7	513.0
		PII(M12+D21)	51	50	98.0	89.6	100	662.2	458.3	956.6
	2VT/VT/12	PRE	49	1	2.0	0.1	10.9	5.2	4.8	5.6
		PI(D21)	49	26	53.1	38.3	67.5	16.7	11.3	24.7
		PII(D42)	43	39	90.7	77.9	97.4	179.1	117.2	273.6
		PII(M6)	45	33	73.3	58.1	85.4	25.0	17.7	35.3
		PII(M12)	41	23	56.1	39.7	71.5	14.2	10.1	20.1
		PIII(M12+D7)	40	37	92.5	79.6	98.4	257.7	162.4	409.0
		PIII(M12+D21)	40	38	95.0	83.1	99.4	441.0	279.5	695.9
	2VT/IN/12	PRE	48	0	0.0	0.0	7.4	5.0	5.0	5.0
		PI(D21)	48	26	54.2	39.2	68.6	18.9	12.6	28.2
		PII(D42)	42	39	92.9	80.5	98.5	228.1	141.8	367.1
		PII(M6)	45	35	77.8	62.9	88.8	35.6	24.2	52.5
		PII(M12)	44	26	59.1	43.2	73.7	17.4	11.6	25.9
		PIII(M12+D7)	43	40	93.0	80.9	98.5	358.2	228.7	561.1
		PIII(M12+D21)	43	43	100	91.8	100	942.2	703.1	1262.7
A/Indonesia	VT/VT/12	PRE	55	0	0.0	0.0	6.5	5.0	5.0	5.0
		PI(D21)	55	7	12.7	5.3	24.5	6.4	5.2	7.9
		PI(M6)	53	2	3.8	0.5	13.0	5.4	4.8	6.1
		PI(M12)	52	5	9.6	3.2	21.0	5.8	5.0	6.8
		PII(M12+D7)	50	44	88.0	75.7	95.5	97.8	66.5	143.8
		PII(M12+D21)	50	45	90.0	78.2	96.7	139.3	92.0	211.0
	VT/IN/12	PRE	53	0	0.0	0.0	6.7	5.0	5.0	5.0
		PI(D21)	53	9	17.0	8.1	29.8	7.0	5.6	8.7
		PI(M6)	53	6	11.3	4.3	23.0	5.8	5.1	6.6

		PI(M12)	52	6	11.5	4.4	23.4	5.9	5.1	6.8
		PII(M12+D7)	51	47	92.2	81.1	97.8	196.2	128.6	299.2
		PII(M12+D21)	51	49	96.1	86.5	99.5	420.0	283.8	621.6
	2VT/VT/12	PRE	49	0	0.0	0.0	7.3	5.0	5.0	5.0
		PI(D21)	49	4	8.2	2.3	19.6	5.4	5.0	5.8
		PII(D42)	43	25	58.1	42.1	73.0	18.1	12.4	26.4
		PII(M6)	45	11	24.4	12.9	39.5	6.4	5.6	7.3
		PII(M12)	41	4	9.8	2.7	23.1	5.7	5.0	6.5
		PIII(M12+D7)	40	35	87.5	73.2	95.8	106.5	66.7	170.0
		PIII(M12+D21)	40	37	92.5	79.6	98.4	191.9	121.6	303.0
	2VT/IN/12	PRE	48	0	0.0	0.0	7.4	5.0	5.0	5.0
		PI(D21)	48	5	10.4	3.5	22.7	5.8	5.0	6.6
		PII(D42)	42	30	71.4	55.4	84.3	29.4	18.1	47.7
		PII(M6)	45	20	44.4	29.6	60.0	10.5	7.7	14.2
		PII(M12)	44	13	29.5	16.8	45.2	8.4	6.4	11.1
		PIII(M12+D7)	43	39	90.7	77.9	97.4	239.4	149.9	382.2
		PIII(M12+D21)	43	43	100	91.8	100	624.9	469.3	831.9

GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95%CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M12)= Post-vaccination dose 2 at Month 12

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 HI antibodies titers against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains for adults who received booster dose at Month 6 (ATP cohort for Persistence)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:10**				**GMT**		
				n	**%**	**95%CI**		**value**	**95%CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam	VT/IN/6	PRE	51	0	0.0	0.0	7.0	5.0	5.0	5.0
		PI(D21)	51	29	56.9	42.2	70.7	20.7	13.9	30.7
		PI(M6)	50	23	46.0	31.8	60.7	11.6	8.6	15.5
		PII(M6+D7)	48	47	97.9	88.9	99.9	209.0	152.7	286.2
		PII(M6+D21)	47	46	97.9	88.7	99.9	411.1	291.3	580.3
		PII(M12)	45	39	86.7	73.2	94.9	66.0	43.0	101.1
		PII(M18)	44	30	68.2	52.4	81.4	24.3	16.3	36.4
	VT/VT/6	PRE	49	1	2.0	0.1	10.9	5.2	4.8	5.6
		PI(D21)	49	24	49.0	34.4	63.7	15.8	10.9	23.0
		PI(M6)	44	16	36.4	22.4	52.2	9.7	7.3	12.9
		PII(M6+D7)	42	38	90.5	77.4	97.3	215.4	137.8	336.6
		PII(M6+D21)	43	39	90.7	77.9	97.4	317.4	197.5	510.1
		PII(M12)	43	35	81.4	66.6	91.6	63.8	40.6	100.3
		PII(M18)	42	26	61.9	45.6	76.4	25.7	16.3	40.4
	2VT/IN/6	PRE	47	1	2.1	0.1	11.3	5.2	4.8	5.7
		PI(D21)	47	31	66.0	50.7	79.1	34.3	21.4	55.0
		PII(D42)	41	38	92.7	80.1	98.5	220.6	145.4	334.6
		PII(M6)	46	33	71.7	56.5	84.0	29.6	19.7	44.4

		PIII(M6+D7)	45	41	91.1	78.8	97.5	191.0	117.3	311.0
		PIII(M6+D21)	46	44	95.7	85.2	99.5	542.1	340.8	862.5
		PIII(M12)	45	39	86.7	73.2	94.9	107.1	66.4	172.8
		PIII(M18)	46	36	78.3	63.6	89.1	45.1	28.8	70.7
	2VT/VT/6	PRE	44	2	4.5	0.6	15.5	5.8	4.7	7.2
		PI(D21)	44	27	61.4	45.5	75.6	30.8	18.2	52.2
		PII(D42)	39	37	94.9	82.7	99.4	275.1	178.2	424.7
		PII(M6)	44	30	68.2	52.4	81.4	31.3	20.2	48.5
		PIII(M6+D7)	42	38	90.5	77.4	97.3	211.7	133.0	337.0
		PIII(M6+D21)	42	39	92.9	80.5	98.5	359.2	220.2	585.9
		PIII(M12)	42	37	88.1	74.4	96.0	101.6	62.4	165.3
		PIII(M18)	40	30	75.0	58.8	87.3	46.4	27.7	77.7
A/Indonesia	VT/IN/6	PRE	51	0	0.0	0.0	7.0	5.0	5.0	5.0
		PI(D21)	51	8	15.7	7.0	28.6	6.5	5.4	7.7
		PI(M6)	50	4	8.0	2.2	19.2	5.5	5.0	6.1
		PII(M6+D7)	48	47	97.9	88.9	99.9	142.6	102.7	197.9
		PII(M6+D21)	47	46	97.9	88.7	99.9	290.8	202.1	418.3
		PII(M12)	45	35	77.8	62.9	88.8	44.6	28.6	69.5
		PII(M18)	44	30	68.2	52.4	81.4	31.1	20.3	47.5
	VT/VT/6	PRE	49	0	0.0	0.0	7.3	5.0	5.0	5.0
		PI(D21)	49	6	12.2	4.6	24.8	5.6	5.1	6.0
		PI(M6)	44	2	4.5	0.6	15.5	5.3	4.9	5.7
		PII(M6+D7)	42	33	78.6	63.2	89.7	64.5	40.1	103.7
		PII(M6+D21)	43	37	86.0	72.1	94.7	97.9	63.3	151.2
		PII(M12)	43	25	58.1	42.1	73.0	17.6	11.8	26.2
		PII(M18)	42	26	61.9	45.6	76.4	19.8	13.3	29.7
	2VT/IN/6	PRE	47	0	0.0	0.0	7.5	5.0	5.0	5.0
		PI(D21)	47	6	12.8	4.8	25.7	6.3	5.2	7.6
		PII(D42)	41	25	61.0	44.5	75.8	22.5	14.8	34.3
		PII(M6)	46	17	37.0	23.2	52.5	8.5	6.4	11.2
		PIII(M6+D7)	45	39	86.7	73.2	94.9	124.1	75.2	204.8
		PIII(M6+D21)	46	44	95.7	85.2	99.5	383.5	245.2	599.7
		PIII(M12)	45	33	73.3	58.1	85.4	56.6	33.7	95.0
		PIII(M18)	46	36	78.3	63.6	89.1	50.6	32.0	79.9
	2VT/VT/6	PRE	44	0	0.0	0.0	8.0	5.0	5.0	5.0
		PI(D21)	44	4	9.1	2.5	21.7	5.4	5.0	5.8
		PII(D42)	39	20	51.3	34.8	67.6	16.7	10.8	25.8
		PII(M6)	44	11	25.0	13.2	40.3	7.0	5.8	8.4
		PIII(M6+D7)	42	34	81.0	65.9	91.4	59.9	38.1	94.3
		PIII(M6+D21)	42	37	88.1	74.4	96.0	120.9	76.9	190.1
		PIII(M12)	42	24	57.1	41.0	72.3	23.8	14.5	38.9
		PIII(M18)	40	25	62.5	45.8	77.3	28.3	17.0	47.0

GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95%CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42
PI(M6) = Post-vaccination dose 1 at Month 6
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6

PII(M12) = Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 HI antibodies titers against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains for adults who received booster dose at Month 12 (ATP cohort for Persistence)

Antibodies against	Group	Timing	N	≥ 1:10				GMT		
				n	%	95%CI		value	95%CI	
						LL	UL		LL	UL
A/Vietnam	VT/IN/12	PRE	49	0	0.0	0.0	7.3	5.0	5.0	5.0
		PI(D21)	49	26	53.1	38.3	67.5	21.3	13.5	33.8
		PI(M6)	49	21	42.9	28.8	57.8	12.8	8.9	18.5
		PI(M12)	48	17	35.4	22.2	50.5	10.1	7.3	14.0
		PII(M12+D7)	47	47	100	92.5	100	387.6	272.3	551.7
		PII(M12+D21)	47	47	100	92.5	100	752.8	542.4	1044.8
		PII(M18)	45	39	86.7	73.2	94.9	115.8	71.9	186.3
	VT/VT/12	PRE	53	1	1.9	0.0	10.1	5.1	4.9	5.4
		PI(D21)	53	28	52.8	38.6	66.7	17.9	12.2	26.1
		PI(M6)	51	20	39.2	25.8	53.9	9.7	7.4	12.8
		PI(M12)	50	14	28.0	16.2	42.5	8.0	6.2	10.3
		PII(M12+D7)	48	44	91.7	80.0	97.7	236.3	151.8	367.9
		PII(M12+D21)	48	45	93.8	82.8	98.7	351.5	226.3	545.9
		PII(M18)	49	40	81.6	68.0	91.2	76.1	47.1	123.1
	2VT/IN/12	PRE	45	0	0.0	0.0	7.9	5.0	5.0	5.0
		PI(D21)	45	25	55.6	40.0	70.4	19.8	13.1	30.2
		PII(D42)	39	36	92.3	79.1	98.4	222.3	133.7	369.5
		PII(M6)	42	33	78.6	63.2	89.7	36.8	24.6	55.2
		PII(M12)	41	25	61.0	44.5	75.8	18.7	12.3	28.4
		PIII(M12+D7)	40	37	92.5	79.6	98.4	348.9	216.6	562.1
		PIII(M12+D21)	40	40	100	91.2	100	978.4	720.6	1328.5
		PIII(M18)	39	38	97.4	86.5	99.9	337.5	219.5	518.9
	2VT/VT/12	PRE	49	1	2.0	0.1	10.9	5.2	4.8	5.6
		PI(D21)	49	26	53.1	38.3	67.5	16.7	11.3	24.7
		PII(D42)	43	39	90.7	77.9	97.4	179.1	117.2	273.6
		PII(M6)	45	33	73.3	58.1	85.4	25.0	17.7	35.3
		PII(M12)	41	23	56.1	39.7	71.5	14.2	10.1	20.1
		PIII(M12+D7)	40	37	92.5	79.6	98.4	257.7	162.4	409.0
		PIII(M12+D21)	40	38	95.0	83.1	99.4	441.0	279.5	695.9
		PIII(M18)	40	37	92.5	79.6	98.4	149.3	93.0	239.6
A/Indonesia	VT/IN/12	PRE	49	0	0.0	0.0	7.3	5.0	5.0	5.0
		PI(D21)	49	8	16.3	7.3	29.7	6.7	5.4	8.2
		PI(M6)	49	5	10.2	3.4	22.2	5.7	5.1	6.4
		PI(M12)	48	5	10.4	3.5	22.7	5.9	5.1	6.8
		PII(M12+D7)	47	44	93.6	82.5	98.7	208.6	136.0	320.0
		PII(M12+D21)	47	46	97.9	88.7	99.9	466.2	321.0	677.2
		PII(M18)	45	39	86.7	73.2	94.9	139.3	85.7	226.6
	VT/VT/12	PRE	53	0	0.0	0.0	6.7	5.0	5.0	5.0
		PI(D21)	53	7	13.2	5.5	25.3	6.5	5.2	8.0
		PI(M6)	51	2	3.9	0.5	13.5	5.4	4.8	6.1
		PI(M12)	50	5	10.0	3.3	21.8	5.9	5.0	6.8
		PII(M12+D7)	48	42	87.5	74.8	95.3	99.3	66.7	148.0
		PII(M12+D21)	48	43	89.6	77.3	96.5	139.5	90.7	214.4
		PII(M18)	49	38	77.6	63.4	88.2	56.6	35.5	90.2

	2VT/IN/12	PRE	45	0	0.0	0.0	7.9	5.0	5.0	5.0
		PI(D21)	45	5	11.1	3.7	24.1	5.8	5.0	6.7
		PII(D42)	39	29	74.4	57.9	87.0	31.9	19.2	53.0
		PII(M6)	42	20	47.6	32.0	63.6	11.0	8.0	15.2
		PII(M12)	41	13	31.7	18.1	48.1	8.7	6.5	11.7
		PIII(M12+D7)	40	36	90.0	76.3	97.2	238.3	144.8	392.4
		PIII(M12+D21)	40	40	100	91.2	100	651.3	482.5	879.2
		PIII(M18)	39	38	97.4	86.5	99.9	385.9	252.9	588.6
	2VT/VT/12	PRE	49	0	0.0	0.0	7.3	5.0	5.0	5.0
		PI(D21)	49	4	8.2	2.3	19.6	5.4	5.0	5.8
		PII(D42)	43	25	58.1	42.1	73.0	18.1	12.4	26.4
		PII(M6)	45	11	24.4	12.9	39.5	6.4	5.6	7.3
		PII(M12)	41	4	9.8	2.7	23.1	5.7	5.0	6.5
		PIII(M12+D7)	40	35	87.5	73.2	95.8	106.5	66.7	170.0
		PIII(M12+D21)	40	37	92.5	79.6	98.4	191.9	121.6	303.0
		PIII(M18)	40	36	90.0	76.3	97.2	121.3	76.6	192.0

GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95%CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42
PI(M6) = Post-vaccination dose 1 at Month 6
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PI(M12) = Post-vaccination dose 1 at Month 12
PII(M12) = Post-vaccination dose 2 at Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): SCR for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12 +21 days, for adults who received the booster dose at Month 12 – Pre-vaccination time point as Day 0 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Vietnam	VT/VT/12	PI(D21)	55	23	41.8	28.7	55.9
		PI(M6)	53	9	17.0	8.1	29.8
		PI(M12)	52	6	11.5	4.4	23.4
		PII(M12+D7)	50	45	90.0	78.2	96.7
		PII(M12+D21)	50	46	92.0	80.8	97.8
	VT/IN/12	PI(D21)	53	23	43.4	29.8	57.7
		PI(M6)	53	13	24.5	13.8	38.3
		PI(M12)	52	10	19.2	9.6	32.5
		PII(M12+D7)	51	49	96.1	86.5	99.5
		PII(M12+D21)	51	50	98.0	89.6	100
	2VT/VT/12	PI(D21)	49	15	30.6	18.3	45.4
		PII(D42)	43	39	90.7	77.9	97.4
		PII(M6)	45	22	48.9	33.7	64.2
		PII(M12)	41	9	22.0	10.6	37.6
		PIII(M12+D7)	40	37	92.5	79.6	98.4
		PIII(M12+D21)	40	38	95.0	83.1	99.4

	2VT/IN/12	PI(D21)	48	21	43.8	29.5	58.8
		PII(D42)	42	38	90.5	77.4	97.3
		PII(M6)	45	30	66.7	51.0	80.0
		PII(M12)	44	17	38.6	24.4	54.5
		PIII(M12+D7)	43	40	93.0	80.9	98.5
		PIII(M12+D21)	43	43	100	91.8	100
A/Indonesia	VT/VT/12	PI(D21)	55	3	5.5	1.1	15.1
		PI(M6)	53	1	1.9	0.0	10.1
		PI(M12)	52	2	3.8	0.5	13.2
		PII(M12+D7)	50	40	80.0	66.3	90.0
		PII(M12+D21)	50	42	84.0	70.9	92.8
	VT/IN/12	PI(D21)	53	5	9.4	3.1	20.7
		PI(M6)	53	0	0.0	0.0	6.7
		PI(M12)	52	2	3.8	0.5	13.2
		PII(M12+D7)	51	44	86.3	73.7	94.3
		PII(M12+D21)	51	49	96.1	86.5	99.5
	2VT/VT/12	PI(D21)	49	0	0.0	0.0	7.3
		PII(D42)	43	18	41.9	27.0	57.9
		PII(M6)	45	0	0.0	0.0	7.9
		PII(M12)	41	0	0.0	0.0	8.6
		PIII(M12+D7)	40	34	85.0	70.2	94.3
		PIII(M12+D21)	40	36	90.0	76.3	97.2
	2VT/IN/12	PI(D21)	48	1	2.1	0.1	11.1
		PII(D42)	42	21	50.0	34.2	65.8
		PII(M6)	45	7	15.6	6.5	29.5
		PII(M12)	44	5	11.4	3.8	24.6
		PIII(M12+D7)	43	39	90.7	77.9	97.4
		PIII(M12+D21)	43	43	100	91.8	100

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): SCR for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12, for adults who received the booster dose at Month 6 – Pre-vaccination time point as Day 0 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Vietnam	VT/VT/6	PI(D21)	50	19	38.0	24.7	52.8
		PI(M6)	45	5	11.1	3.7	24.1
		PII(M12)	43	33	76.7	61.4	88.2
	VT/IN/6	PI(D21)	53	24	45.3	31.6	59.6
		PI(M6)	52	13	25.0	14.0	38.9

		PII(M12)	47	35	74.5	59.7	86.1
	2VT/VT/6	PI(D21)	45	23	51.1	35.8	66.3
		PII(D42)	39	36	92.3	79.1	98.4
		PII(M6)	45	25	55.6	40.0	70.4
		PIII(M12)	43	32	74.4	58.8	86.5
	2VT/IN/6	PI(D21)	49	29	59.2	44.2	73.0
		PII(D42)	43	40	93.0	80.9	98.5
		PII(M6)	48	25	52.1	37.2	66.7
		PIII(M12)	46	37	80.4	66.1	90.6
A/Indonesia	VT/VT/6	PI(D21)	50	0	0.0	0.0	7.1
		PI(M6)	45	0	0.0	0.0	7.9
		PII(M12)	43	16	37.2	23.0	53.3
	VT/IN/6	PI(D21)	53	3	5.7	1.2	15.7
		PI(M6)	52	0	0.0	0.0	6.8
		PII(M12)	47	29	61.7	46.4	75.5
	2VT/VT/6	PI(D21)	45	0	0.0	0.0	7.9
		PII(D42)	39	15	38.5	23.4	55.4
		PII(M6)	45	2	4.4	0.5	15.1
		PIII(M12)	43	19	44.2	29.1	60.1
	2VT/IN/6	PI(D21)	49	3	6.1	1.3	16.9
		PII(D42)	43	23	53.5	37.7	68.8
		PII(M6)	48	4	8.3	2.3	20.0
		PIII(M12)	46	31	67.4	52.0	80.5

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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
PRE= Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12)= Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): SCR for H5N1 HI antibodies titers against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 6 + Day 7, Month 6 + Day 21 and Month 18 for adults who received booster dose at Month 6 – pre-vaccination time point as Month 6 (ATP cohort for Persistence)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Vietnam	VT/IN/6	PII(M6+D7)	48	43	89.6	77.3	96.5
		PII(M6+D21)	47	46	97.9	88.7	99.9
		PII(M18)	44	11	25.0	13.2	40.3
	VT/VT/6	PII(M6+D7)	42	36	85.7	71.5	94.6
		PII(M6+D21)	43	38	88.4	74.9	96.1
		PII(M18)	42	15	35.7	21.6	52.0
	2VT/IN/6	PIII(M6+D7)	45	29	64.4	48.8	78.1
		PIII(M6+D21)	46	41	89.1	76.4	96.4
		PIII(M18)	46	9	19.6	9.4	33.9
	2VT/VT/6	PIII(M6+D7)	42	27	64.3	48.0	78.4
		PIII(M6+D21)	42	34	81.0	65.9	91.4
		PIII(M18)	40	7	17.5	7.3	32.8
A/Indonesia	VT/IN/6	PII(M6+D7)	48	43	89.6	77.3	96.5

		PII(M6+D21)	47	46	97.9	88.7	99.9
		PII(M18)	44	26	59.1	43.2	73.7
	VT/VT/6	PII(M6+D7)	42	31	73.8	58.0	86.1
		PII(M6+D21)	43	35	81.4	66.6	91.6
		PII(M18)	42	18	42.9	27.7	59.0
	2VT/IN/6	PIII(M6+D7)	45	38	84.4	70.5	93.5
		PIII(M6+D21)	46	42	91.3	79.2	97.6
		PIII(M18)	46	28	60.9	45.4	74.9
	2VT/VT/6	PIII(M6+D7)	42	28	66.7	50.5	80.4
		PIII(M6+D21)	42	35	83.3	68.6	93.0
		PIII(M18)	40	20	50.0	33.8	66.2

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): SCR for H5N1 HI antibodies titers against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 12 + Day 7, Month 12 + Day 21 and Month 18 for adults who received booster dose at Month 12 – pre-vaccination time point as Month 12 (ATP cohort for Persistence)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Vietnam	VT/IN/12	PII(M12+D7)	47	43	91.5	79.6	97.6
		PII(M12+D21)	47	47	100	92.5	100
		PII(M18)	44	30	68.2	52.4	81.4
	VT/VT/12	PII(M12+D7)	48	41	85.4	72.2	93.9
		PII(M12+D21)	48	42	87.5	74.8	95.3
		PII(M18)	48	33	68.8	53.7	81.3
	2VT/IN/12	PIII(M12+D7)	40	35	87.5	73.2	95.8
		PIII(M12+D21)	40	40	100	91.2	100
		PIII(M18)	39	34	87.2	72.6	95.7
	2VT/VT/12	PIII(M12+D7)	40	34	85.0	70.2	94.3
		PIII(M12+D21)	40	37	92.5	79.6	98.4
		PIII(M18)	40	29	72.5	56.1	85.4
A/Indonesia	VT/IN/12	PII(M12+D7)	47	40	85.1	71.7	93.8
		PII(M12+D21)	47	46	97.9	88.7	99.9
		PII(M18)	44	39	88.6	75.4	96.2
	VT/VT/12	PII(M12+D7)	48	37	77.1	62.7	88.0
		PII(M12+D21)	48	39	81.3	67.4	91.1
		PII(M18)	48	34	70.8	55.9	83.0
	2VT/IN/12	PIII(M12+D7)	40	36	90.0	76.3	97.2
		PIII(M12+D21)	40	40	100	91.2	100
		PIII(M18)	39	37	94.9	82.7	99.4
	2VT/VT/12	PIII(M12+D7)	40	34	85.0	70.2	94.3
		PIII(M12+D21)	40	36	90.0	76.3	97.2
		PIII(M18)	40	34	85.0	70.2	94.3

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination

For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): Booster SCR for H5N1 HI antibodies against A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12 + 21 Days, for adults who received the booster dose at Month 12 – Pre-booster time point as Month 12 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	Booster SCR			
				n	%	95%CI	
						LL	UL
A/Vietnam/	VT/VT/12	PII(M12+D7)	50	43	86.0	73.3	94.2
		PII(M12+D21)	50	44	88.0	75.7	95.5
	VT/IN/12	PII(M12+D7)	51	46	90.2	78.6	96.7
		PII(M12+D21)	51	50	98.0	89.6	100
	2VT/VT/12	PIII(M12+D7)	40	34	85.0	70.2	94.3
		PIII(M12+D21)	40	37	92.5	79.6	98.4
	2VT/IN/12	PIII(M12+D7)	43	38	88.4	74.9	96.1
		PIII(M12+D21)	43	43	100	91.8	100
A/Indonesia	VT/VT/12	PII(M12+D7)	50	38	76.0	61.8	86.9
		PII(M12+D21)	50	41	82.0	68.6	91.4
	VT/IN/12	PII(M12+D7)	51	43	84.3	71.4	93.0
		PII(M12+D21)	51	49	96.1	86.5	99.5
	2VT/VT/12	PIII(M12+D7)	40	34	85.0	70.2	94.3
		PIII(M12+D21)	40	36	90.0	76.3	97.2
	2VT/IN/12	PIII(M12+D7)	43	39	90.7	77.9	97.4
		PIII(M12+D21)	43	43	100	91.8	100

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12

Secondary Outcome Variable(s): Booster SCR for H5N1 HI antibody response against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 18 for subjects who received booster dose at Month 6 – pre-vaccination time point as Month 6 (ATP cohort for Persistence)

Antibodies against	Group	N	Booster SCR			
			n	%	95%CI	
					LL	UL
A/Vietnam	VT/IN/6	44	11	25.0	13.2	40.3
	VT/VT/6	42	15	35.7	21.6	52.0
	2VT/IN/6	46	9	19.6	9.4	33.9
	2VT/VT/6	40	7	17.5	7.3	32.8
A/Indonesia	VT/IN/6	44	26	59.1	43.2	73.7
	VT/VT/6	42	18	42.9	27.7	59.0
	2VT/IN/6	46	28	60.9	45.4	74.9

	2VT/VT/6	40	20	50.0	33.8	66.2

Total = subjects either seropositive or seronegative at pre-vaccination
Booster SCR defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 at PII(M18) OR PIII(M18)
For initially seropositive subjects: antibody titer at PII(M18) OR PIII(M18) ≥ 4 fold the pre-vaccination antibody titer
N = number of subjects with both pre- and post-vaccination results available
n/% = number/percentage of responders
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): Booster SCR for H5N1 HI antibody response against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 18 for subjects who received booster dose at Month 12 –pre-vaccination time point as Month 12 (ATP cohort for Persistence)

Antibodies against	Group	N	Booster SCR			
			n	%	95%CI	
					LL	UL
A/Vietnam	VT/IN/12	44	30	68.2	52.4	81.4
	VT/VT/12	48	33	68.8	53.7	81.3
	2VT/IN/12	39	34	87.2	72.6	95.7
	2VT/VT/12	40	29	72.5	56.1	85.4
A/Indonesia	VT/IN/12	44	39	88.6	75.4	96.2
	VT/VT/12	48	34	70.8	55.9	83.0
	2VT/IN/12	39	37	94.9	82.7	99.4
	2VT/VT/12	40	34	85.0	70.2	94.3

Total = subjects either seropositive or seronegative at pre-vaccination
Booster response defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 at PII(M18) OR PIII(M18)
For initially seropositive subjects: antibody titer at PII(M18) OR PIII(M18) ≥ 4 fold the pre-vaccination antibody titer
N = number of subjects with both pre- and post-vaccination results available
n/% = number/percentage of responders
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable(s): SCF for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12 + 21 Days, for adults who received the booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCF		
				Value	95%CI	
					LL	UL
A/Vietnam	VT/VT/12	PI(D21)	55	3.6	2.5	5.2
		PI(M12)	52	1.6	1.3	2.1
		PII(M12+D7)	50	45.9	29.8	70.7
		PII(M12+D21)	50	68.6	44.5	105.8
	VT/IN/12	PI(D21)	53	4.1	2.6	6.3
		PI(M12)	52	2.0	1.5	2.7
		PII(M12+D7)	51	70.9	48.9	102.6
		PII(M12+D21)	51	132.4	91.7	191.3
	2VT/VT/12	PI(D21)	49	3.2	2.2	4.8
		PII(D42)	43	34.4	22.7	52.2
		PII(M12)	41	2.7	1.9	3.9
		PIII(M12+D7)	40	49.4	31.0	78.6
		PIII(M12+D21)	40	84.5	53.3	133.9
	2VT/IN/12	PI(D21)	48	3.8	2.5	5.6
		PII(D42)	42	45.6	28.4	73.4
		PII(M12)	44	3.5	2.3	5.2
		PIII(M12+D7)	43	71.6	45.7	112.2
		PIII(M12+D21)	43	188.4	140.6	252.5
A/Indonesia	VT/VT/12	PI(D21)	55	1.3	1.0	1.6
		PI(M12)	52	1.2	1.0	1.4
		PII(M12+D7)	50	19.6	13.3	28.8

		PII(M12+D21)	50	27.9	18.4	42.2
	VT/IN/12	PI(D21)	53	1.4	1.1	1.7
		PI(M12)	52	1.2	1.0	1.4
		PII(M12+D7)	51	39.2	25.7	59.8
		PII(M12+D21)	51	84.0	56.8	124.3
	2VT/VT/12	PI(D21)	49	1.1	1.0	1.2
		PII(D42)	43	3.6	2.5	5.3
		PII(M12)	41	1.1	1.0	1.3
		PIII(M12+D7)	40	21.3	13.3	34.0
		PIII(M12+D21)	40	38.4	24.3	60.6
	2VT/IN/12	PI(D21)	48	1.2	1.0	1.3
		PII(D42)	42	5.9	3.6	9.5
		PII(M12)	44	1.7	1.3	2.2
		PIII(M12+D7)	43	47.9	30.0	76.4
		PIII(M12+D21)	43	125.0	93.9	166.4

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): SCF for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12, for adults who received the booster dose at Month 6 (ATP cohort for Immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCF**		
				Value	**95%CI**	
					LL	**UL**
A/Vietnam	VT/VT/6	PI(D21)	66	3.0	2.2	4.0
		PI(M6)	60	1.7	1.4	2.1
		PII(M12)	58	9.6	6.3	14.7
	VT/IN/6	PI(D21)	63	4.0	2.8	5.8
		PI(M6)	60	2.4	1.8	3.2
		PII(M12)	54	14.3	9.6	21.4
	2VT/VT/6	PI(D21)	61	5.7	3.8	8.5
		PII(D42)	52	50.3	34.8	72.7
		PII(M6)	61	6.4	4.5	8.9
		PIII(M12)	56	19.0	12.9	28.1
	2VT/IN/6	PI(D21)	64	5.4	3.8	7.9
		PII(D42)	54	40.8	27.5	60.5
		PII(M6)	63	6.0	4.3	8.5
		PIII(M12)	60	22.5	14.5	34.9
A/Indonesia	VT/VT/6	PI(D21)	66	1.1	1.0	1.2
		PI(M6)	60	1.0	1.0	1.1
		PII(M12)	58	2.9	2.1	4.0
	VT/IN/6	PI(D21)	63	1.3	1.1	1.5
		PI(M6)	60	1.1	1.0	1.3
		PII(M12)	54	8.9	5.8	13.6
	2VT/VT/6	PI(D21)	61	1.1	1.0	1.3
		PII(D42)	52	4.1	2.8	6.0

		PII(M6)	61	1.6	1.4	2.0
		PIII(M12)	56	5.5	3.7	8.3
	2VT/IN/6	PI(D21)	64	1.2	1.0	1.4
		PII(D42)	54	4.6	3.2	6.8
		PII(M6)	63	1.6	1.3	2.0
		PIII(M12)	60	11.6	7.4	18.2

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12)= Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): SCF for H5N1 HI antibodies titers against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 6 + Day 7, Month 6 + Day 21 and Month 18 for adults who received booster dose at Month 6 – pre-vaccination time point as Month 6 (ATP cohort for Persistence)

Antibodies against	Group	Timing	N	SCF		
				Value	95%CI	
					LL	UL
A/Vietnam	VTI/N6	PII(M18)	44	2.1	1.5	3.1
		PII(M6+D7)	48	17.5	12.1	25.1
		PII(M6+D21)	47	34.7	23.9	50.5
	VT/VT/6	PII(M18)	42	2.7	1.7	4.2
		PII(M6+D7)	42	21.6	13.1	35.5
		PII(M6+D21)	43	32.3	19.8	52.7
	2VT/IN/6	PIII(M18)	46	1.5	1.1	2.2
		PIII(M6+D7)	45	6.5	4.1	10.4
		PIII(M6+D21)	46	18.3	11.6	28.9
	2VT/VT/6	PIII(M18)	40	1.5	0.9	2.3
		PIII(M6+D7)	42	6.6	4.1	10.6
		PIII(M6+D21)	42	11.0	6.8	17.9
A/Indonesia	VT/IN/6	PII(M18)	44	5.7	3.7	8.5
		PII(M6+D7)	48	25.8	18.5	36.0
		PII(M6+D21)	47	52.5	36.7	75.0
	VT/VT/6	PII(M18)	42	3.7	2.5	5.7
		PII(M6+D7)	42	12.2	7.6	19.6
		PII(M6+D21)	43	18.5	11.9	28.8
	2VT/IN/6	PIII(M18)	46	6.0	4.0	9.0
		PIII(M6+D7)	45	14.9	8.6	26.0
		PIII(M6+D21)	46	45.3	29.9	68.5
	2VT/VT/6	PIII(M18)	40	4.3	2.7	6.7
		PIII(M6+D7)	42	8.6	5.6	13.2
		PIII(M6+D21)	42	17.5	11.2	27.4

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): SCF for H5N1 HI antibodies titers against A/Vietnam/1194/2004 and

A/Indonesia/05/2005 strains at Month 12 + Day 7, Month 12 + Day 21 and Month 18 for adults who received booster dose at Month 12 – pre-vaccination time point as Month 12 (ATP cohort for Persistence)

Antibodies against	Group	Timing	N	SCF		
				Value	95%CI	
					LL	UL
A/Vietnam	VT/IN/12	PII(M12+D7)	47	37.9	24.0	59.8
		PII(M12+D21)	47	73.6	47.9	113.3
		PII(M18)	44	12.0	7.3	19.8
	VT/VT/12	PII(M12+D7)	48	28.9	18.1	46.3
		PII(M12+D21)	48	43.1	26.6	69.6
		PII(M18)	48	10.2	6.4	16.1
	2VT/IN/12	PIII(M12+D7)	40	19.9	11.2	35.3
		PIII(M12+D21)	40	55.7	36.4	85.3
		PIII(M18)	39	18.6	11.1	31.2
	2VT/VT/12	PIII(M12+D7)	40	17.6	10.8	28.8
		PIII(M12+D21)	40	30.2	18.6	48.8
		PIII(M18)	40	10.2	6.2	16.8
A/Indonesia	VT/IN/12	PII(M12+D7)	47	35.2	22.4	55.4
		PII(M12+D21)	47	78.7	52.9	117.2
		PII(M18)	44	25.1	15.8	39.8
	VT/VT/12	PII(M12+D7)	48	16.8	11.2	25.2
		PII(M12+D21)	48	23.6	15.4	36.3
		PII(M18)	48	10.3	6.6	16.0
	2VT/IN/12	PIII(M12+D7)	40	27.9	15.8	49.2
		PIII(M12+D21)	40	76.2	53.2	109.0
		PIII(M18)	39	44.5	27.9	71.0
	2VT/VT/12	PIII(M12+D7)	40	18.7	11.7	29.9
		PIII(M12+D21)	40	33.7	21.0	54.1
		PIII(M18)	40	21.3	13.2	34.4

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): SPR for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SPR			
				n	%	95%CI	
						LL	UL
A/Vietnam	VT/VT/6	PRE	50	0	0.0	0.0	7.1
		PI(D21)	50	19	38.0	24.7	52.8
		PI(M6)	45	6	13.3	5.1	26.8
		PII(M6+D7)	43	39	90.7	77.9	97.4
		PII(M6+D21)	44	40	90.9	78.3	97.5
		PII(M12)	43	33	76.7	61.4	88.2
	VT/IN/6	PRE	53	0	0.0	0.0	6.7
		PI(D21)	53	24	45.3	31.6	59.6
		PI(M6)	52	13	25.0	14.0	38.9
		PII(M6+D7)	50	49	98.0	89.4	99.9
		PII(M6+D21)	49	48	98.0	89.1	99.9
		PII(M12)	47	35	74.5	59.7	86.1

	2VT/VT/6	PRE	45	2	4.4	0.5	15.1
		PI(D21)	45	24	53.3	37.9	68.3
		PII(D42)	39	36	92.3	79.1	98.4
		PII(M6)	45	26	57.8	42.2	72.3
		PIII(M6+D7)	43	38	88.4	74.9	96.1
		PIII(M6+D21)	43	39	90.7	77.9	97.4
		PIII(M12)	43	33	76.7	61.4	88.2
	2VT/IN/6	PRE	49	1	2.0	0.1	10.9
		PI(D21)	49	29	59.2	44.2	73.0
		PII(D42)	43	40	93.0	80.9	98.5
		PII(M6)	48	25	52.1	37.2	66.7
		PIII(M6+D7)	47	42	89.4	76.9	96.5
		PIII(M6+D21)	48	45	93.8	82.8	98.7
		PIII(M12)	46	37	80.4	66.1	90.6
A/Indonesia	VT/VT/6	PRE	50	0	0.0	0.0	7.1
		PI(D21)	50	0	0.0	0.0	7.1
		PI(M6)	45	0	0.0	0.0	7.9
		PII(M6+D7)	43	32	74.4	58.8	86.5
		PII(M6+D21)	44	37	84.1	69.9	93.4
		PII(M12)	43	16	37.2	23.0	53.3
	VT/IN/6	PRE	53	0	0.0	0.0	6.7
		PI(D21)	53	3	5.7	1.2	15.7
		PI(M6)	52	0	0.0	0.0	6.8
		PII(M6+D7)	50	46	92.0	80.8	97.8
		PII(M6+D21)	49	48	98.0	89.1	99.9
		PII(M12)	47	29	61.7	46.4	75.5
	2VT/VT/6	PRE	45	0	0.0	0.0	7.9
		PI(D21)	45	0	0.0	0.0	7.9
		PII(D42)	39	15	38.5	23.4	55.4
		PII(M6)	45	2	4.4	0.5	15.1
		PIII(M6+D7)	43	31	72.1	56.3	84.7
		PIII(M6+D21)	43	37	86.0	72.1	94.7
		PIII(M12)	43	19	44.2	29.1	60.1
	2VT/IN/6	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	3	6.1	1.3	16.9
		PII(D42)	43	23	53.5	37.7	68.8
		PII(M6)	48	4	8.3	2.3	20.0
		PIII(M6+D7)	47	40	85.1	71.7	93.8
		PIII(M6+D21)	48	45	93.8	82.8	98.7
		PIII(M12)	46	31	67.4	52.0	80.5

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12))= Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): SPR for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005

strains up to Month 12 + 21 Days, for adults who received the booster dose at Month 12 (ATP cohort for Immunogenicity)							
Antibodies against	**Group**	**Timing**	**N**	**SPR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Vietnam	VT/VT/12	PRE	55	0	0.0	0.0	6.5
		PI(D21)	55	23	41.8	28.7	55.9
		PI(M6)	53	9	17.0	8.1	29.8
		PI(M12)	52	6	11.5	4.4	23.4
		PII(M12+D7)	50	45	90.0	78.2	96.7
		PII(M12+D21)	50	46	92.0	80.8	97.8
	VT/IN/12	PRE	53	0	0.0	0.0	6.7
		PI(D21)	53	23	43.4	29.8	57.7
		PI(M6)	53	13	24.5	13.8	38.3
		PI(M12)	52	10	19.2	9.6	32.5
		PII(M12+D7)	51	49	96.1	86.5	99.5
		PII(M12+D21)	51	50	98.0	89.6	100
	2VT/VT/12	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	16	32.7	19.9	47.5
		PII(D42)	43	39	90.7	77.9	97.4
		PII(M6)	45	22	48.9	33.7	64.2
		PII(M12)	41	9	22.0	10.6	37.6
		PIII(M12+D7)	40	37	92.5	79.6	98.4
		PIII(M12+D21)	40	38	95.0	83.1	99.4
	2VT/IN/12	PRE	48	0	0.0	0.0	7.4
		PI(D21)	48	21	43.8	29.5	58.8
		PII(D42)	42	38	90.5	77.4	97.3
		PII(M6)	45	30	66.7	51.0	80.0
		PII(M12)	44	17	38.6	24.4	54.5
		PIII(M12+D7)	43	40	93.0	80.9	98.5
		PIII(M12+D21)	43	43	100	91.8	100
A/Indonesia	VT/VT/12	PRE	55	0	0.0	0.0	6.5
		PI(D21)	55	3	5.5	1.1	15.1
		PI(M6)	53	1	1.9	0.0	10.1
		PI(M12)	52	2	3.8	0.5	13.2
		PII(M12+D7)	50	40	80.0	66.3	90.0
		PII(M12+D21)	50	42	84.0	70.9	92.8
	VT/IN/12	PRE	53	0	0.0	0.0	6.7
		PI(D21)	53	5	9.4	3.1	20.7
		PI(M6)	53	0	0.0	0.0	6.7
		PI(M12)	52	2	3.8	0.5	13.2
		PII(M12+D7)	51	44	86.3	73.7	94.3
		PII(M12+D21)	51	49	96.1	86.5	99.5
	2VT/VT/12	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	0	0.0	0.0	7.3
		PII(D42)	43	18	41.9	27.0	57.9
		PII(M6)	45	0	0.0	0.0	7.9
		PII(M12)	41	0	0.0	0.0	8.6
		PIII(M12+D7)	40	34	85.0	70.2	94.3
		PIII(M12+D21)	40	36	90.0	76.3	97.2
	2VT/IN/12	PRE	48	0	0.0	0.0	7.4
		PI(D21)	48	1	2.1	0.1	11.1
		PII(D42)	42	21	50.0	34.2	65.8
		PII(M6)	45	7	15.6	6.5	29.5
		PII(M12)	44	5	11.4	3.8	24.6

		PIII(M12+D7)	43	39	90.7	77.9	97.4
		PIII(M12+D21)	43	43	100	91.8	100

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M12)= Post-vaccination dose 2 at Month 12

Secondary Outcome Variable(s): SPR for H5N1 HI antibodies titers against A/Indonesia/1194/2004 and A/Vietnam/05/2005 strains for adults who received booster dose at Month 6 (ATP cohort for Persistence)

Antibodies against	**Group**	**Timing**	**N**	**SPR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Vietnam	VT/IN/6	PRE	51	0	0.0	0.0	7.0
		PI(D21)	51	23	45.1	31.1	59.7
		PI(M6)	50	12	24.0	13.1	38.2
		PII(M6+D7)	48	47	97.9	88.9	99.9
		PII(M6+D21)	47	46	97.9	88.7	99.9
		PII(M12)	45	34	75.6	60.5	87.1
		PII(M18)	44	21	47.7	32.5	63.3
	VT/VT/6	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	18	36.7	23.4	51.7
		PI(M6)	44	6	13.6	5.2	27.4
		PII(M6+D7)	42	38	90.5	77.4	97.3
		PII(M6+D21)	43	39	90.7	77.9	97.4
		PII(M12)	43	33	76.7	61.4	88.2
		PII(M18)	42	24	57.1	41.0	72.3
	2VT/IN/6	PRE	47	1	2.1	0.1	11.3
		PI(D21)	47	28	59.6	44.3	73.6
		PII(D42)	41	38	92.7	80.1	98.5
		PII(M6)	46	24	52.2	36.9	67.1
		PIII(M6+D7)	45	40	88.9	75.9	96.3
		PIII(M6+D21)	46	43	93.5	82.1	98.6
		PIII(M12)	45	36	80.0	65.4	90.4
		PIII(M18)	46	30	65.2	49.8	78.6
	2VT/VT/6	PRE	44	2	4.5	0.6	15.5
		PI(D21)	44	23	52.3	36.7	67.5
		PII(D42)	39	36	92.3	79.1	98.4
		PII(M6)	44	25	56.8	41.0	71.7
		PIII(M6+D7)	42	37	88.1	74.4	96.0
		PIII(M6+D21)	42	38	90.5	77.4	97.3
		PIII(M12)	42	32	76.2	60.5	87.9
		PIII(M18)	40	24	60.0	43.3	75.1
A/Indonesia	VT/IN/6	PRE	51	0	0.0	0.0	7.0
		PI(D21)	51	3	5.9	1.2	16.2
		PI(M6)	50	0	0.0	0.0	7.1
		PII(M6+D7)	48	44	91.7	80.0	97.7
		PII(M6+D21)	47	46	97.9	88.7	99.9

		PII(M12)	45	29	64.4	48.8	78.1
		PII(M18)	44	26	59.1	43.2	73.7
	VT/VT/6	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	0	0.0	0.0	7.3
		PI(M6)	44	0	0.0	0.0	8.0
		PII(M6+D7)	42	31	73.8	58.0	86.1
		PII(M6+D21)	43	36	83.7	69.3	93.2
		PII(M12)	43	16	37.2	23.0	53.3
		PII(M18)	42	18	42.9	27.7	59.0
	2VT/IN/6	PRE	47	0	0.0	0.0	7.5
		PI(D21)	47	3	6.4	1.3	17.5
		PII(D42)	41	22	53.7	37.4	69.3
		PII(M6)	46	4	8.7	2.4	20.8
		PIII(M6+D7)	45	38	84.4	70.5	93.5
		PIII(M6+D21)	46	43	93.5	82.1	98.6
		PIII(M12)	45	30	66.7	51.0	80.0
		PIII(M18)	46	30	65.2	49.8	78.6
	2VT/VT/6	PRE	44	0	0.0	0.0	8.0
		PI(D21)	44	0	0.0	0.0	8.0
		PII(D42)	39	15	38.5	23.4	55.4
		PII(M6)	44	2	4.5	0.6	15.5
		PIII(M6+D7)	42	30	71.4	55.4	84.3
		PIII(M6+D21)	42	36	85.7	71.5	94.6
		PIII(M12)	42	18	42.9	27.7	59.0
		PIII(M18)	40	21	52.5	36.1	68.5

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42
PI(M6) = Post-vaccination dose 1 at Month 6
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M12) = Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): SPR for H5N1 HI antibodies titers against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains for adults who received booster dose at Month 12 (ATP cohort for Persistence)

Antibodies against	**Group**	**Timing**	**N**	**SPR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Vietnam	VT/IN/12	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	22	44.9	30.7	59.8
		PI(M6)	49	12	24.5	13.3	38.9
		PI(M12)	48	9	18.8	8.9	32.6
		PII(M12+D7)	47	46	97.9	88.7	99.9
		PII(M12+D21)	47	47	100	92.5	100
		PII(M18)	45	37	82.2	67.9	92.0
	VT/VT/12	PRE	53	0	0.0	0.0	6.7
		PI(D21)	53	22	41.5	28.1	55.9

		PI(M6)	51	8	15.7	7.0	28.6
		PI(M12)	50	5	10.0	3.3	21.8
		PII(M12+D7)	48	43	89.6	77.3	96.5
		PII(M12+D21)	48	44	91.7	80.0	97.7
		PII(M18)	49	37	75.5	61.1	86.7
	2VT/IN/12	PRE	45	0	0.0	0.0	7.9
		PI(D21)	45	21	46.7	31.7	62.1
		PII(D42)	39	35	89.7	75.8	97.1
		PII(M6)	42	28	66.7	50.5	80.4
		PII(M12)	41	17	41.5	26.3	57.9
		PIII(M12+D7)	40	37	92.5	79.6	98.4
		PIII(M12+D21)	40	40	100	91.2	100
		PIII(M18)	39	38	97.4	86.5	99.9
	2VT/VT/12	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	16	32.7	19.9	47.5
		PII(D42)	43	39	90.7	77.9	97.4
		PII(M6)	45	22	48.9	33.7	64.2
		PII(M12)	41	9	22.0	10.6	37.6
		PIII(M12+D7)	40	37	92.5	79.6	98.4
		PIII(M12+D21)	40	38	95.0	83.1	99.4
		PIII(M18)	40	34	85.0	70.2	94.3
A/Indonesia	VT/IN/12	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	4	8.2	2.3	19.6
		PI(M6)	49	0	0.0	0.0	7.3
		PI(M12)	48	2	4.2	0.5	14.3
		PII(M12+D7)	47	41	87.2	74.3	95.2
		PII(M12+D21)	47	46	97.9	88.7	99.9
		PII(M18)	45	39	86.7	73.2	94.9
	VT/VT/12	PRE	53	0	0.0	0.0	6.7
		PI(D21)	53	3	5.7	1.2	15.7
		PI(M6)	51	1	2.0	0.0	10.4
		PI(M12)	50	2	4.0	0.5	13.7
		PII(M12+D7)	48	39	81.3	67.4	91.1
		PII(M12+D21)	48	40	83.3	69.8	92.5
		PII(M18)	49	34	69.4	54.6	81.7
	2VT/IN/12	PRE	45	0	0.0	0.0	7.9
		PI(D21)	45	1	2.2	0.1	11.8
		PII(D42)	39	20	51.3	34.8	67.6
		PII(M6)	42	7	16.7	7.0	31.4
		PII(M12)	41	5	12.2	4.1	26.2
		PIII(M12+D7)	40	36	90.0	76.3	97.2
		PIII(M12+D21)	40	40	100	91.2	100
		PIII(M18)	39	38	97.4	86.5	99.9
	2VT/VT/12	PRE	49	0	0.0	0.0	7.3
		PI(D21)	49	0	0.0	0.0	7.3
		PII(D42)	43	18	41.9	27.0	57.9
		PII(M6)	45	0	0.0	0.0	7.9
		PII(M12)	41	0	0.0	0.0	8.6
		PIII(M12+D7)	40	34	85.0	70.2	94.3
		PIII(M12+D21)	40	36	90.0	76.3	97.2
		PIII(M18)	40	35	87.5	73.2	95.8

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

PRE = Pre-vaccination at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42
PI(M6) = Post-vaccination dose 1 at Month 6
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PI(M12) = Post-vaccination dose 1 at Month 12
PII(M12) = Post-vaccination dose 2 at Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): BF for H5N1 HI antibodies against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12 + 21 days, for adults who received the booster dose at Month 12 - Pre booster timepoint as Month 12 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	BF		
				Value	95%CI	
					LL	UL
A/Vietnam	VT/VT/12	PII(M12+D7)	50	27.5	17.4	43.5
		PII(M12+D21)	50	41.1	25.8	65.4
	VT/IN/12	PII(M12+D7)	51	35.2	22.4	55.3
		PII(M12+D21)	51	65.8	42.2	102.6
	2VT/VT/12	PIII(M12+D7)	40	17.6	10.8	28.8
		PIII(M12+D21)	40	30.2	18.6	48.8
	2VT/IN/12	PIII(M12+D7)	43	21.9	12.7	37.9
		PIII(M12+D21)	43	57.6	38.6	86.1
A/Indonesia	VT/VT/12	PII(M12+D7)	50	16.7	11.3	24.7
		PII(M12+D21)	50	23.8	15.7	35.9
	VT/IN/12	PII(M12+D7)	51	33.1	21.3	51.6
		PII(M12+D21)	51	70.9	47.0	107.0
	2VT/VT/12	PIII(M12+D7)	40	18.7	11.7	29.9
		PIII(M12+D21)	40	33.7	21.0	54.1
	2VT/IN/12	PIII(M12+D7)	43	29.1	17.0	49.6
		PIII(M12+D21)	43	75.8	54.2	106.1

N = Number of subjects with pre- and post-vaccination results available
Booster Factor (BF) = Seroconversion Factor booster (mean[log10(POST/M12)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12

Secondary Outcome Variable(s): Booster seroconversion factors (Booster SCFs) for H5N1 HI antibodies against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 12 + Day 7, Month 12 + Day 21 and Month 18 for subjects who received booster dose at Month 12 – pre-booster time point as Month 12 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	Booster SCF		
				Value	95% CI	
					LL	UL
A/Vietnam	VT/IN/12	PII(M12+D7)	47	37.9	24.0	59.8
		PII(M12+D21)	47	73.6	47.9	113.3
		PII(M18)	44	12.0	7.3	19.8
	VT/VT/12	PII(M12+D7)	48	28.9	18.1	46.3
		PII(M12+D21)	48	43.1	26.6	69.6
		PII(M18)	48	10.2	6.4	16.1
	2VT/IN/12	PIII(M12+D7)	40	19.9	11.2	35.3

		PIII(M12+D21)	40	55.7	36.4	85.3
		PIII(M18)	39	18.6	11.1	31.2
	2VT/VT/12	PIII(M12+D7)	40	17.6	10.8	28.8
		PIII(M12+D21)	40	30.2	18.6	48.8
		PIII(M18)	40	10.2	6.2	16.8
A/Indonesia	VT/IN/12	PII(M12+D7)	47	35.2	22.4	55.4
		PII(M12+D21)	47	78.7	52.9	117.2
		PII(M18)	44	25.1	15.8	39.8
	VT/VT/12	PII(M12+D7)	48	16.8	11.2	25.2
		PII(M12+D21)	48	23.6	15.4	36.3
		PII(M18)	48	10.3	6.6	16.0
	2VT/IN/12	PIII(M12+D7)	40	27.9	15.8	49.2
		PIII(M12+D21)	40	76.2	53.2	109.0
		PIII(M18)	39	44.5	27.9	71.0
	2VT/VT/12	PIII(M12+D7)	40	18.7	11.7	29.9
		PIII(M12+D21)	40	33.7	21.0	54.1
		PIII(M18)	40	21.3	13.2	34.4

N = Number of subjects with pre- and post-booster results available
Booster SCF = Booster Seroconversion Factor or geometric mean ratio (mean[log10(POST/M12)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): GMTs of neutralizing antibody titers against A/Indonesia/05/05 and A/Vietnam/1194/04 strains at Days 0, Day 21, Day 42, Month 6, Month 6 + 7 days and Month 6 + 21 days for subjects who received booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:28**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Indonesia	VT/IN/6	PRE	56	8	14.3	6.4	26.2	15.7	14.5	17.0
		PI(D21)	56	42	75.0	61.6	85.6	39.8	32.4	48.8
		PI(M6)	55	20	36.4	23.8	50.4	22.0	18.2	26.6
		PII(M6+D7)	53	53	100	93.3	100	966.7	762.0	1226.3
		PII(M6+D21)	51	51	100	93.0	100	1815.5	1368.0	2409.3
	VT/VT/6	PRE	55	4	7.3	2.0	17.6	15.5	13.9	17.2
		PI(D21)	55	37	67.3	53.3	79.3	32.0	26.6	38.5
		PI(M6)	49	19	38.8	25.2	53.8	21.7	18.1	25.9
		PII(M6+D7)	47	47	100	92.5	100	512.4	411.8	637.6
		PII(M6+D21)	47	47	100	92.5	100	674.4	536.9	847.1
	2VT/IN/6	PRE	50	5	10.0	3.3	21.8	15.4	14.1	16.9
		PI(D21)	7	5	71.4	29.0	96.3	37.9	18.1	79.6
		PII(D42)	44	40	90.9	78.3	97.5	87.9	68.1	113.4
		PII(M6)	49	34	69.4	54.6	81.7	41.7	31.2	55.7
		PIII(M6+D7)	48	48	100	92.6	100	1016.1	759.5	1359.4
		PIII(M6+D21)	49	49	100	92.7	100	2334.1	1712.4	3181.4
	2VT/VT/6	PRE	48	2	4.2	0.5	14.3	14.4	13.8	15.0
		PI(D21)	11	7	63.6	30.8	89.1	33.3	19.1	58.2
		PII(D42)	38	36	94.7	82.3	99.4	75.9	59.4	96.9
		PII(M6)	48	27	56.3	41.2	70.5	30.5	23.7	39.3
		PIII(M6+D7)	46	46	100	92.3	100	562.0	457.2	690.8
		PIII(M6+D21)	43	43	100	91.8	100	831.3	644.7	1071.8
A/Vietnam	VT/IN/6	PRE	56	15	26.8	15.8	40.3	20.4	16.9	24.8

		PI(D21)	56	55	98.2	90.4	100	117.9	91.8	151.5
		PI(M6)	55	40	72.7	59.0	83.9	39.7	30.8	51.0
		PII(M6+D7)	53	53	100	93.3	100	778.7	623.8	972.1
		PII(M6+D21)	52	52	100	93.2	100	1392.3	1065.5	1819.2
	VT/VT/6	PRE	55	18	32.7	20.7	46.7	22.2	17.8	27.6
		PI(D21)	55	55	100	93.5	100	106.7	86.7	131.2
		PI(M6)	49	41	83.7	70.3	92.7	39.2	31.2	49.2
		PII(M6+D7)	47	47	100	92.5	100	1113.9	857.8	1446.5
		PII(M6+D21)	47	47	100	92.5	100	1435.9	1074.8	1918.4
	2VT/IN/6	PRE	50	10	20.0	10.0	33.7	18.9	15.8	22.7
		PI(D21)	7	7	100	59.0	100	179.6	93.5	345.0
		PII(D42)	44	44	100	92.0	100	372.3	286.5	483.8
		PII(M6)	49	48	98.0	89.1	99.9	88.8	64.0	123.1
		PIII(M6+D7)	48	48	100	92.6	100	945.3	729.8	1224.5
		PIII(M6+D21)	49	49	100	92.7	100	1922.0	1436.1	2572.4
	2VT/VT/6	PRE	48	13	27.1	15.3	41.8	19.8	16.2	24.1
		PI(D21)	7	6	85.7	42.1	99.6	78.8	28.3	219.8
		PII(D42)	41	41	100	91.4	100	429.8	319.1	578.9
		PII(M6)	48	48	100	92.6	100	91.2	71.8	115.9
		PIII(M6+D7)	46	46	100	92.3	100	1058.8	828.7	1352.8
		PIII(M6+D21)	45	45	100	92.1	100	1625.2	1192.6	2214.6

GMT = Geometric Mean antibody Titer
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:28)
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6

Secondary Outcome Variable(s): GMTs of neutralizing antibody titers against A/Indonesia/05/05 and A/Vietnam/1194/04 strains at Days 0, Day 21 and Day 42 for subjects who received booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:28**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Indonesia	VT/IN/12	PRE	59	6	10.2	3.8	20.8	15.8	14.3	17.5
		PI(D21)	58	45	77.6	64.7	87.5	43.5	35.0	54.0
	VT/VT/12	PRE	60	7	11.7	4.8	22.6	15.7	14.4	17.2
		PI(D21)	60	40	66.7	53.3	78.3	37.0	29.2	46.8
	2VT/IN/12	PRE	55	4	7.3	2.0	17.6	15.1	14.0	16.3
		PI(D21)	9	6	66.7	29.9	92.5	31.3	18.3	53.5
		PII(D42)	48	46	95.8	85.7	99.5	97.0	71.2	132.1
	2VT/VT/12	PRE	55	5	9.1	3.0	20.0	15.5	14.1	17.0
		PI(D21)	11	6	54.5	23.4	83.3	26.5	17.1	41.0
		PII(D42)	48	48	100	92.6	100	83.6	67.8	103.0
A/Vietnam	VT/IN/12	PRE	59	16	27.1	16.4	40.3	21.0	17.2	25.5
		PI(D21)	58	57	98.3	90.8	100	124.4	93.8	165.1
	VT/VT/12	PRE	60	20	33.3	21.7	46.7	20.6	17.7	23.9
		PI(D21)	60	58	96.7	88.5	99.6	99.2	80.2	122.6
	2VT/IN/12	PRE	54	14	25.9	15.0	39.7	20.3	16.7	24.6
		PI(D21)	8	8	100	63.1	100	80.2	49.5	129.9
		PII(D42)	48	48	100	92.6	100	500.2	360.5	693.9

	2VT/VT/12	PRE	55	14	25.5	14.7	39.0	20.0	16.4	24.3
		PI(D21)	9	8	88.9	51.8	99.7	104.6	35.3	310.0
		PII(D42)	48	48	100	92.6	100	404.4	321.5	508.7

GMT = Geometric Mean antibody Titer
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:28)
95%CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42

Secondary Outcome Variable(s): Seropositivity rates and GMTs of neutralizing antibody titers against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12, for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:28**				**GMT**		
				n	**%**	**95%CI**		**value**	**95%CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam	VT/IN/6	PRE	53	14	26.4	15.3	40.3	20.6	16.8	25.2
		PI(D21)	53	52	98.1	89.9	100	120.3	93.3	155.1
		PI(M6)	52	37	71.2	56.9	82.9	36.5	28.9	46.1
		PII(M6+D7)	50	50	100	92.9	100	730.5	584.7	912.6
		PII(M6+D21)	49	49	100	92.7	100	1283.1	984.1	1672.9
		PII(M12)	47	47	100	92.5	100	646.3	539.0	775.0
	VT/VT/6	PRE	50	16	32.0	19.5	46.7	21.8	17.4	27.2
		PI(D21)	50	50	100	92.9	100	109.1	87.7	135.7
		PI(M6)	45	38	84.4	70.5	93.5	39.5	31.1	50.3
		PII(M6+D7)	43	43	100	91.8	100	1204.9	920.6	1576.9
		PII(M6+D21)	43	43	100	91.8	100	1607.4	1208.5	2137.9
		PII(M12)	42	42	100	91.6	100	762.9	611.3	952.1
	2VT/IN/6	PRE	49	10	20.4	10.2	34.3	19.1	15.9	22.9
		PI(D21)	7	7	100	59.0	100	179.6	93.5	345.0
		PII(D42)	43	43	100	91.8	100	355.1	276.6	456.0
		PII(M6)	48	47	97.9	88.9	99.9	87.1	62.5	121.3
		PIII(M6+D7)	47	47	100	92.5	100	927.9	714.2	1205.5
		PIII(M6+D21)	48	48	100	92.6	100	1879.1	1400.3	2521.6
		PIII(M12)	46	45	97.8	88.5	99.9	795.6	577.1	1097.0
	2VT/VT/6	PRE	45	13	28.9	16.4	44.3	20.2	16.4	24.9
		PI(D21)	6	6	100	54.1	100	105.1	41.6	265.4
		PII(D42)	39	39	100	91.0	100	449.3	338.8	596.0
		PII(M6)	45	45	100	92.1	100	90.4	71.8	113.9
		PIII(M6+D7)	43	43	100	91.8	100	1042.6	805.2	1350.0
		PIII(M6+D21)	42	42	100	91.6	100	1613.4	1174.7	2215.8
		PIII(M12)	43	42	97.7	87.7	99.9	823.6	600.5	1129.6
A/Indonesia	VT/IN/6	PRE	53	7	13.2	5.5	25.3	15.6	14.4	17.0
		PI(D21)	53	40	75.5	61.7	86.2	40.5	32.7	50.2
		PI(M6)	52	18	34.6	22.0	49.1	20.7	17.4	24.5
		PII(M6+D7)	50	50	100	92.9	100	901.6	711.5	1142.5
		PII(M6+D21)	48	48	100	92.6	100	1682.1	1263.6	2239.2
		PII(M12)	47	47	100	92.5	100	672.9	527.4	858.7
	VT/VT/6	PRE	50	3	6.0	1.3	16.5	15.3	13.7	17.0
		PI(D21)	50	33	66.0	51.2	78.8	31.8	26.1	38.8
		PI(M6)	45	18	40.0	25.7	55.7	21.9	18.2	26.5
		PII(M6+D7)	43	43	100	91.8	100	538.5	429.4	675.2
		PII(M6+D21)	43	43	100	91.8	100	719.2	567.6	911.3
		PII(M12)	42	42	100	91.6	100	392.1	329.2	467.0
	2VT/IN/6	PRE	49	5	10.2	3.4	22.2	15.5	14.1	16.9
		PI(D21)	7	5	71.4	29.0	96.3	37.9	18.1	79.6

		PII(D42)	43	39	90.7	77.9	97.4	86.0	66.4	111.2
		PII(M6)	48	33	68.8	53.7	81.3	41.2	30.7	55.3
		PIII(M6+D7)	47	47	100	92.5	100	994.1	740.9	1334.0
		PIII(M6+D21)	48	48	100	92.6	100	2279.9	1667.7	3116.9
		PIII(M12)	46	46	100	92.3	100	1003.8	751.2	1341.4
	2VT/VT/6	PRE	45	2	4.4	0.5	15.1	14.4	13.8	15.1
		PI(D21)	10	7	70.0	34.8	93.3	36.3	20.2	65.4
		PII(D42)	36	35	97.2	85.5	99.9	76.7	61.0	96.3
		PII(M6)	45	25	55.6	40.0	70.4	29.5	22.9	37.9
		PIII(M6+D7)	43	43	100	91.8	100	546.6	439.8	679.5
		PIII(M6+D21)	40	40	100	91.2	100	821.4	638.9	1055.9
		PIII(M12)	43	42	97.7	87.7	99.9	540.0	406.6	717.3

GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): Seropositivity rates and GMTs of neutralizing antibody titers against the A/Vietnam/1194/2004/1194/2004 or A/Indonesia/05/2005 strains up to Month 12 + 21 Days, for adults who received the booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:28**				**GMT**		
				n	**%**	**95%CI**		**value**	**95%CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam	VT/IN/12	PRE	53	13	24.5	13.8	38.3	20.4	16.7	25.1
		PI(D21)	53	52	98.1	89.9	100	120.2	91.6	157.8
		PI(M6)	53	52	98.1	89.9	100	270.6	216.5	338.2
		PI(M12)	52	50	96.2	86.8	99.5	551.9	431.3	706.4
		PII(M12+D7)	51	51	100	93.0	100	1848.1	1453.8	2349.4
		PII(M12+D21)	51	51	100	93.0	100	3209.7	2461.3	4185.6
	VT/VT/12	PRE	55	19	34.5	22.2	48.6	20.9	17.8	24.6
		PI(D21)	55	53	96.4	87.5	99.6	102.6	81.8	128.7
		PI(M6)	53	53	100	93.3	100	223.2	191.7	259.9
		PI(M12)	51	50	98.0	89.6	100	504.0	412.6	615.7
		PII(M12+D7)	49	49	100	92.7	100	1448.5	1175.5	1784.9
		PII(M12+D21)	50	50	100	92.9	100	2520.3	1914.2	3318.3
	2VT/IN/12	PRE	47	12	25.5	13.9	40.3	20.3	16.4	25.1
		PI(D21)	8	8	100	63.1	100	80.2	49.5	129.9
		PII(D42)	41	41	100	91.4	100	486.6	340.2	696.0
		PII(M6)	45	44	97.8	88.2	99.9	401.9	302.2	534.4
		PII(M12)	44	44	100	92.0	100	474.3	395.3	568.9
		PIII(M12+D7)	43	43	100	91.8	100	2002.2	1533.7	2613.9
		PIII(M12+D21)	43	43	100	91.8	100	3874.7	2944.6	5098.5
	2VT/VT/12	PRE	49	13	26.5	14.9	41.1	20.5	16.5	25.4
		PI(D21)	8	7	87.5	47.3	99.7	116.2	33.9	398.1
		PII(D42)	43	43	100	91.8	100	399.2	321.7	495.4
		PII(M6)	45	45	100	92.1	100	334.2	267.0	418.3

		PII(M12)	41	41	100	91.4	100	468.1	405.1	540.8
		PIII(M12+D7)	40	40	100	91.2	100	1718.1	1301.3	2268.4
		PIII(M12+D21)	40	40	100	91.2	100	2304.8	1747.6	3039.5
A/Indonesia	VT/IN/12	PRE	53	6	11.3	4.3	23.0	16.1	14.3	18.0
		PI(D21)	53	41	77.4	63.8	87.7	44.9	35.6	56.7
		PI(M6)	53	47	88.7	77.0	95.7	144.2	107.2	194.0
		PI(M12)	52	48	92.3	81.5	97.9	124.7	93.8	165.8
		PII(M12+D7)	51	51	100	93.0	100	2025.2	1505.1	2725.1
		PII(M12+D21)	51	50	98.0	89.6	100	3254.2	2325.5	4553.9
	VT/VT/12	PRE	55	7	12.7	5.3	24.5	15.9	14.5	17.5
		PI(D21)	55	39	70.9	57.1	82.4	39.7	31.0	50.8
		PI(M6)	53	51	96.2	87.0	99.5	122.4	99.2	150.9
		PI(M12)	51	44	86.3	73.7	94.3	106.5	80.2	141.5
		PII(M12+D7)	49	49	100	92.7	100	936.9	730.9	1200.9
		PII(M12+D21)	50	50	100	92.9	100	1301.5	984.4	1720.7
	2VT/IN/12	PRE	48	4	8.3	2.3	20.0	15.3	14.0	16.7
		PI(D21)	9	6	66.7	29.9	92.5	31.3	18.3	53.5
		PII(D42)	41	39	95.1	83.5	99.4	99.9	70.0	142.7
		PII(M6)	45	43	95.6	84.9	99.5	259.6	195.6	344.5
		PII(M12)	44	44	100	92.0	100	234.6	196.7	279.9
		PIII(M12+D7)	42	42	100	91.6	100	2556.6	1917.7	3408.4
		PIII(M12+D21)	43	43	100	91.8	100	4602.2	3621.0	5849.3
	2VT/VT/12	PRE	49	5	10.2	3.4	22.2	15.7	14.1	17.5
		PI(D21)	10	5	50.0	18.7	81.3	26.3	16.1	43.0
		PII(D42)	43	43	100	91.8	100	80.7	65.4	99.6
		PII(M6)	44	44	100	92.0	100	196.3	165.1	233.5
		PII(M12)	41	40	97.6	87.1	99.9	197.5	155.0	251.6
		PIII(M12+D7)	40	40	100	91.2	100	1102.4	770.2	1577.8
		PIII(M12+D21)	40	40	100	91.2	100	1708.3	1277.3	2284.8

N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination dose 1 at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): Seropositivity rates and GMTs of neutralizing antibody titers against the A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at each time point for adults who received the booster dose at Month 6 (ATP cohort for Persistence)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:28**				**GMT**		
				n	**%**	**95%CI**		**value**	**95%CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam	VT/IN/6	PRE	51	14	27.5	15.9	41.7	20.9	17.0	25.8
		PI(D21)	51	50	98.0	89.6	100	119.0	91.5	154.7
		PI(M6)	50	35	70.0	55.4	82.1	35.9	28.2	45.6
		PII(M6+D7)	48	48	100	92.6	100	727.6	579.8	913.0
		PII(M6+D21)	47	47	100	92.5	100	1296.1	985.1	1705.3
		PII(M12)	45	45	100	92.1	100	643.3	532.4	777.4
		PII(M18)	44	44	100	92.0	100	277.7	208.2	370.3

	VT/VT/6	PRE	49	16	32.7	19.9	47.5	22.0	17.5	27.6
		PI(D21)	49	49	100	92.7	100	109.0	87.2	136.2
		PI(M6)	44	37	84.1	69.9	93.4	39.8	31.1	51.0
		PII(M6+D7)	42	42	100	91.6	100	1167.5	893.0	1526.2
		PII(M6+D21)	42	42	100	91.6	100	1568.2	1176.0	2091.2
		PII(M12)	42	42	100	91.6	100	762.9	611.3	952.1
		PII(M18)	42	42	100	91.6	100	338.1	254.2	449.6
	2VT/IN/6	PRE	47	10	21.3	10.7	35.7	19.3	16.0	23.4
		PI(D21)	7	7	100	59.0	100	179.6	93.5	345.0
		PII(D42)	41	41	100	91.4	100	352.9	272.3	457.4
		PII(M6)	46	45	97.8	88.5	99.9	86.1	61.6	120.4
		PIII(M6+D7)	45	45	100	92.1	100	910.3	700.4	1183.1
		PIII(M6+D21)	46	46	100	92.3	100	1863.6	1387.9	2502.4
		PIII(M12)	45	44	97.8	88.2	99.9	797.7	574.3	1107.9
		PIII(M18)	46	46	100	92.3	100	358.9	254.4	506.2
	2VT/VT/6	PRE	44	13	29.5	16.8	45.2	20.4	16.5	25.2
		PI(D21)	5	5	100	47.8	100	103.6	30.4	352.5
		PII(D42)	39	39	100	91.0	100	449.3	338.8	596.0
		PII(M6)	44	44	100	92.0	100	91.4	72.2	115.6
		PIII(M6+D7)	42	42	100	91.6	100	1035.0	794.6	1348.1
		PIII(M6+D21)	41	41	100	91.4	100	1609.1	1162.2	2227.7
		PIII(M12)	42	41	97.6	87.4	99.9	844.7	613.7	1162.7
		PIII(M18)	40	40	100	91.2	100	444.5	310.4	636.6
A/Indonesia	VT/IN/6	PRE	51	7	13.7	5.7	26.3	15.7	14.4	17.1
		PI(D21)	51	38	74.5	60.4	85.7	40.6	32.5	50.6
		PI(M6)	50	17	34.0	21.2	48.8	20.7	17.4	24.7
		PII(M6+D7)	48	48	100	92.6	100	906.1	708.4	1158.8
		PII(M6+D21)	46	46	100	92.3	100	1703.0	1263.7	2295.0
		PII(M12)	45	45	100	92.1	100	678.0	525.5	874.7
		PII(M18)	44	44	100	92.0	100	361.1	283.8	459.6
	VT/VT/6	PRE	49	3	6.1	1.3	16.9	15.3	13.7	17.1
		PI(D21)	49	32	65.3	50.4	78.3	31.8	25.9	38.9
		PI(M6)	44	18	40.9	26.3	56.8	22.2	18.3	26.8
		PII(M6+D7)	42	42	100	91.6	100	526.2	419.4	660.2
		PII(M6+D21)	42	42	100	91.6	100	707.6	556.5	899.8
		PII(M12)	42	42	100	91.6	100	392.1	329.2	467.0
		PII(M18)	42	42	100	91.6	100	225.0	175.0	289.2
	2VT/IN/6	PRE	47	5	10.6	3.5	23.1	15.5	14.2	17.1
		PI(D21)	7	5	71.4	29.0	96.3	37.9	18.1	79.6
		PII(D42)	41	37	90.2	76.9	97.3	86.3	66.5	111.9
		PII(M6)	46	32	69.6	54.2	82.3	40.9	30.3	55.0
		PIII(M6+D7)	45	45	100	92.1	100	963.3	713.9	1299.9
		PIII(M6+D21)	46	46	100	92.3	100	2224.0	1613.6	3065.3
		PIII(M12)	45	45	100	92.1	100	995.8	740.6	1339.0
		PIII(M18)	46	46	100	92.3	100	447.6	345.2	580.5
	2VT/VT/6	PRE	44	2	4.5	0.6	15.5	14.4	13.8	15.1
		PI(D21)	9	6	66.7	29.9	92.5	36.4	18.6	71.1
		PII(D42)	36	35	97.2	85.5	99.9	76.7	61.0	96.3
		PII(M6)	44	24	54.5	38.8	69.6	29.2	22.6	37.7
		PIII(M6+D7)	42	42	100	91.6	100	537.3	431.1	669.5
		PIII(M6+D21)	39	39	100	91.0	100	814.7	629.8	1053.8
		PIII(M12)	42	41	97.6	87.4	99.9	533.4	399.2	712.8
		PIII(M18)	40	39	97.5	86.8	99.9	290.1	211.1	398.7

N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95%CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PRE = Pre-vaccination at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42
PI(M6) = Post-vaccination dose 1 at Month 6
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M12) = Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): Seropositivity rates and GMTs of neutralizing antibody titers against the A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at each time point for adults who received the booster dose at Month 12 (ATP cohort for Persistence)

Antibodies against	Group	Timing	N	≥ 1:28				GMT		
				n	%	95%CI		value	95%CI	
						LL	UL		LL	UL
A/Vietnam	VT/IN/12	PRE	49	12	24.5	13.3	38.9	20.5	16.5	25.4
		PI(D21)	49	48	98.0	89.1	99.9	123.7	93.6	163.6
		PI(M6)	49	48	98.0	89.1	99.9	274.5	218.3	345.4
		PI(M12)	48	46	95.8	85.7	99.5	542.7	417.6	705.2
		PII(M12+D7)	47	47	100	92.5	100	1945.3	1532.8	2468.9
		PII(M12+D21)	47	47	100	92.5	100	3490.4	2712.8	4491.0
		PII(M18)	44	44	100	92.0	100	813.2	580.8	1138.5
	VT/VT/12	PRE	53	18	34.0	21.5	48.3	20.8	17.7	24.5
		PI(D21)	53	51	96.2	87.0	99.5	103.6	82.1	130.8
		PI(M6)	51	51	100	93.0	100	223.1	190.4	261.4
		PI(M12)	49	48	98.0	89.1	99.9	511.2	415.6	628.9
		PII(M12+D7)	47	47	100	92.5	100	1435.4	1163.3	1771.1
		PII(M12+D21)	48	48	100	92.6	100	2495.4	1886.4	3300.9
		PII(M18)	48	47	97.9	88.9	99.9	585.9	417.5	822.2
	2VT/IN/12	PRE	44	12	27.3	15.0	42.8	20.8	16.6	26.1
		PI(D21)	8	8	100	63.1	100	80.2	49.5	129.9
		PII(D42)	38	38	100	90.7	100	469.2	321.4	684.8
		PII(M6)	42	41	97.6	87.4	99.9	405.1	298.8	549.3
		PII(M12)	41	41	100	91.4	100	475.9	393.1	576.1
		PIII(M12+D7)	40	40	100	91.2	100	1972.2	1490.9	2609.0
		PIII(M12+D21)	40	40	100	91.2	100	4057.4	3048.1	5400.9
		PIII(M18)	39	39	100	91.0	100	1650.0	1203.4	2262.4
	2VT/VT/12	PRE	49	13	26.5	14.9	41.1	20.5	16.5	25.4
		PI(D21)	8	7	87.5	47.3	99.7	116.2	33.9	398.1
		PII(D42)	43	43	100	91.8	100	399.2	321.7	495.4
		PII(M6)	45	45	100	92.1	100	334.2	267.0	418.3
		PII(M12)	41	41	100	91.4	100	468.1	405.1	540.8
		PIII(M12+D7)	40	40	100	91.2	100	1718.1	1301.3	2268.4
		PIII(M12+D21)	40	40	100	91.2	100	2304.8	1747.6	3039.5
		PIII(M18)	40	40	100	91.2	100	871.9	621.0	1224.2
A/Indonesia	VT/IN/12	PRE	49	5	10.2	3.4	22.2	15.9	14.2	17.9
		PI(D21)	49	38	77.6	63.4	88.2	45.1	35.4	57.4
		PI(M6)	49	44	89.8	77.8	96.6	146.5	108.3	198.0
		PI(M12)	48	45	93.8	82.8	98.7	127.0	95.7	168.5
		PII(M12+D7)	47	47	100	92.5	100	2190.6	1657.3	2895.6
		PII(M12+D21)	47	47	100	92.5	100	3722.1	2850.5	4860.1
		PII(M18)	45	45	100	92.1	100	903.0	667.6	1221.5

	VT/VT/12	PRE	53	6	11.3	4.3	23.0	15.6	14.3	17.1
		PI(D21)	53	38	71.7	57.7	83.2	40.0	31.1	51.5
		PI(M6)	51	49	96.1	86.5	99.5	123.3	99.6	152.6
		PI(M12)	49	42	85.7	72.8	94.1	107.8	80.5	144.3
		PII(M12+D7)	47	47	100	92.5	100	947.5	732.7	1225.4
		PII(M12+D21)	48	48	100	92.6	100	1303.0	975.7	1740.0
		PII(M18)	49	49	100	92.7	100	423.7	320.9	559.5
	2VT/IN/12	PRE	45	4	8.9	2.5	21.2	15.4	14.0	16.9
		PI(D21)	9	6	66.7	29.9	92.5	31.3	18.3	53.5
		PII(D42)	38	36	94.7	82.3	99.4	100.8	68.6	148.1
		PII(M6)	42	40	95.2	83.8	99.4	255.0	188.5	345.0
		PII(M12)	41	41	100	91.4	100	231.3	191.6	279.3
		PIII(M12+D7)	39	39	100	91.0	100	2476.1	1839.2	3333.5
		PIII(M12+D21)	40	40	100	91.2	100	4661.0	3625.1	5993.0
		PIII(M18)	39	39	100	91.0	100	1708.9	1243.6	2348.4
	2VT/VT/12	PRE	49	5	10.2	3.4	22.2	15.7	14.1	17.5
		PI(D21)	10	5	50.0	18.7	81.3	26.3	16.1	43.0
		PII(D42)	43	43	100	91.8	100	80.7	65.4	99.6
		PII(M6)	44	44	100	92.0	100	196.3	165.1	233.5
		PII(M12)	41	40	97.6	87.1	99.9	197.5	155.0	251.6
		PIII(M12+D7)	40	40	100	91.2	100	1102.4	770.2	1577.8
		PIII(M12+D21)	40	40	100	91.2	100	1708.3	1277.3	2284.8
		PIII(M18)	40	40	100	91.2	100	620.6	475.5	809.9

N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95%CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D21) = Post-vaccination dose 1 at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42
PI(M6) = Post-vaccination dose 1 at Month 6
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PI(M12) = Post-vaccination dose 1 at Month 12
PII(M12) = Post-vaccination dose 2 at Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): SCR for neutralizing antibody response against A/Indonesia/05/05 and A/Vietnam/1194/04 strains at Day 21, Day 42, Month 6, Month 6 + 7 days and Month 6 + 21 days for subjects who received booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCR			
				n	%	95%CI	
						LL	UL
A/Indonesia	VT/IN/6	PI(D21)	56	19	33.9	21.8	47.8
		PI(M6)	55	6	10.9	4.1	22.2
		PII(M6+D7)	53	53	100	93.3	100
		PII(M6+D21)	51	51	100	93.0	100
	VT/VT/6	PI(D21)	55	13	23.6	13.2	37.0
		PI(M6)	49	5	10.2	3.4	22.2
		PII(M6+D7)	47	46	97.9	88.7	99.9
		PII(M6+D21)	47	47	100	92.5	100
	2VT/IN/6	PI(D21)	7	1	14.3	0.4	57.9
		PII(D42)	44	32	72.7	57.2	85.0
		PII(M6)	49	20	40.8	27.0	55.8

		PIII(M6+D7)	48	48	100	92.6	100
		PIII(M6+D21)	49	49	100	92.7	100
	2VT/VT/6	PI(D21)	11	4	36.4	10.9	69.2
		PII(D42)	38	28	73.7	56.9	86.6
		PII(M6)	48	13	27.1	15.3	41.8
		PIII(M6+D7)	46	46	100	92.3	100
		PIII(M6+D21)	43	43	100	91.8	100
A/Vietnam	VT/IN/6	PI(D21)	56	40	71.4	57.8	82.7
		PI(M6)	55	18	32.7	20.7	46.7
		PII(M6+D7)	53	51	96.2	87.0	99.5
		PII(M6+D21)	52	52	100	93.2	100
	VT/VT/6	PI(D21)	55	34	61.8	47.7	74.6
		PI(M6)	49	10	20.4	10.2	34.3
		PII(M6+D7)	47	45	95.7	85.5	99.5
		PII(M6+D21)	47	45	95.7	85.5	99.5
	2VT/IN/6	PI(D21)	7	5	71.4	29.0	96.3
		PII(D42)	44	42	95.5	84.5	99.4
		PII(M6)	49	28	57.1	42.2	71.2
		PIII(M6+D7)	48	48	100	92.6	100
		PIII(M6+D21)	49	49	100	92.7	100
	2VT/VT/6	PI(D21)	7	5	71.4	29.0	96.3
		PII(D42)	41	39	95.1	83.5	99.4
		PII(M6)	48	31	64.6	49.5	77.8
		PIII(M6+D7)	46	45	97.8	88.5	99.9
		PIII(M6+D21)	45	45	100	92.1	100

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6

Secondary Outcome Variable(s): SCR for neutralizing antibody response against A/Indonesia/05/05 and A/Vietnam/1194/04 strains at Day 21 and Day 42 for subjects who received booster dose at Month 12 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Indonesia	VT/IN/12	PI(D21)	58	19	32.8	21.0	46.3
	VT/VT/12	PI(D21)	60	17	28.3	17.5	41.4
	2VT/IN/12	PI(D21)	9	1	11.1	0.3	48.2
		PII(D42)	48	35	72.9	58.2	84.7
	2VT/VT/12	PI(D21)	11	1	9.1	0.2	41.3
		PII(D42)	48	32	66.7	51.6	79.6
A/Vietnam	VT/IN/12	PI(D21)	58	40	69.0	55.5	80.5
	VT/VT/12	PI(D21)	60	38	63.3	49.9	75.4
	2VT/IN/12	PI(D21)	8	4	50.0	15.7	84.3
		PII(D42)	47	43	91.5	79.6	97.6
	2VT/VT/12	PI(D21)	9	5	55.6	21.2	86.3

		PII(D42)	48	45	93.8	82.8	98.7

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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-vaccination dose 1 at Day 21
PII(D42) = Post-vaccination dose 2 at Day 42

Secondary Outcome Variable(s): SCR of neutralizing antibody titers against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12 +21 days, for adults who received the booster dose at Month 12 – Pre-vaccination time point as Day 0 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCR			
				n	%	95%CI	
						LL	UL
A/Vietnam	VT/IN/12	PI(D21)	53	38	71.7	57.7	83.2
		PI(M6)	53	51	96.2	87.0	99.5
		PI(M12)	52	48	92.3	81.5	97.9
		PII(M12+D7)	51	50	98.0	89.6	100
		PII(M12+D21)	51	51	100	93.0	100
	VT/VT/12	PI(D21)	55	35	63.6	49.6	76.2
		PI(M6)	53	50	94.3	84.3	98.8
		PI(M12)	51	49	96.1	86.5	99.5
		PII(M12+D7)	49	49	100	92.7	100
		PII(M12+D21)	50	50	100	92.9	100
	2VT/IN/12	PI(D21)	8	4	50.0	15.7	84.3
		PII(D42)	40	37	92.5	79.6	98.4
		PII(M6)	44	40	90.9	78.3	97.5
		PII(M12)	43	43	100	91.8	100
		PIII(M12+D7)	42	41	97.6	87.4	99.9
		PIII(M12+D21)	42	42	100	91.6	100
	2VT/VT/12	PI(D21)	8	5	62.5	24.5	91.5
		PII(D42)	43	40	93.0	80.9	98.5
		PII(M6)	45	41	91.1	78.8	97.5
		PII(M12)	41	40	97.6	87.1	99.9
		PIII(M12+D7)	40	40	100	91.2	100
		PIII(M12+D21)	40	39	97.5	86.8	99.9
A/Indonesia	VT/IN/12	PI(D21)	53	18	34.0	21.5	48.3
		PI(M6)	53	45	84.9	72.4	93.3
		PI(M12)	52	41	78.8	65.3	88.9
		PII(M12+D7)	51	51	100	93.0	100
		PII(M12+D21)	51	50	98.0	89.6	100
	VT/VT/12	PI(D21)	55	17	30.9	19.1	44.8
		PI(M6)	53	44	83.0	70.2	91.9
		PI(M12)	51	39	76.5	62.5	87.2
		PII(M12+D7)	49	49	100	92.7	100
		PII(M12+D21)	50	50	100	92.9	100
	2VT/IN/12	PI(D21)	9	1	11.1	0.3	48.2
		PII(D42)	41	30	73.2	57.1	85.8
		PII(M6)	45	43	95.6	84.9	99.5
		PII(M12)	44	42	95.5	84.5	99.4
		PIII(M12+D7)	42	42	100	91.6	100
		PIII(M12+D21)	43	43	100	91.8	100
	2VT/VT/12	PI(D21)	10	1	10.0	0.3	44.5
		PII(D42)	43	28	65.1	49.1	79.0
		PII(M6)	44	44	100	92.0	100

		PII(M12)	41	40	97.6	87.1	99.9
		PIII(M12+D7)	40	40	100	91.2	100
		PIII(M12+D21)	40	40	100	91.2	100

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PI(M12) = Post-vaccination dose1 at Month 12
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): SCR of neutralizing antibody titers against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12, for adults who received the booster dose at Month 6 – Pre-vaccination time point as Day 0 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCR			
				n	%	95%CI	
						LL	UL
A/Vietnam	VT/IN/6	PI(D21)	53	38	71.7	57.7	83.2
		PI(M6)	52	16	30.8	18.7	45.1
		PII(M6+D7)	50	48	96.0	86.3	99.5
		PII(M6+D21)	49	49	100	92.7	100
		PII(M12)	47	47	100	92.5	100
	VT/VT/6	PI(D21)	50	32	64.0	49.2	77.1
		PI(M6)	45	9	20.0	9.6	34.6
		PII(M6+D7)	43	42	97.7	87.7	99.9
		PII(M6+D21)	43	42	97.7	87.7	99.9
		PII(M12)	42	42	100	91.6	100
	2VT/IN/6	PI(D21)	7	5	71.4	29.0	96.3
		PII(D42)	43	41	95.3	84.2	99.4
		PII(M6)	48	27	56.3	41.2	70.5
		PIII(M6+D7)	47	47	100	92.5	100
		PIII(M6+D21)	48	48	100	92.6	100
		PIII(M12)	46	45	97.8	88.5	99.9
	2VT/VT/6	PI(D21)	6	5	83.3	35.9	99.6
		PII(D42)	39	38	97.4	86.5	99.9
		PII(M6)	45	29	64.4	48.8	78.1
		PIII(M6+D7)	43	42	97.7	87.7	99.9
		PIII(M6+D21)	42	42	100	91.6	100
		PIII(M12)	43	42	97.7	87.7	99.9
A/Indonesia	VT/IN/6	PI(D21)	53	19	35.8	23.1	50.2
		PI(M6)	52	4	7.7	2.1	18.5
		PII(M6+D7)	50	50	100	92.9	100
		PII(M6+D21)	48	48	100	92.6	100
		PII(M12)	47	47	100	92.5	100
	VT/VT/6	PI(D21)	50	11	22.0	11.5	36.0
		PI(M6)	45	5	11.1	3.7	24.1
		PII(M6+D7)	43	43	100	91.8	100

		PII(M6+D21)	43	43	100	91.8	100
		PII(M12)	42	42	100	91.6	100
	2VT/IN/6	PI(D21)	7	1	14.3	0.4	57.9
		PII(D42)	43	31	72.1	56.3	84.7
		PII(M6)	48	19	39.6	25.8	54.7
		PIII(M6+D7)	47	47	100	92.5	100
		PIII(M6+D21)	48	48	100	92.6	100
		PIII(M12)	46	46	100	92.3	100
	2VT/VT/6	PI(D21)	10	4	40.0	12.2	73.8
		PII(D42)	36	27	75.0	57.8	87.9
		PII(M6)	45	12	26.7	14.6	41.9
		PIII(M6+D7)	43	43	100	91.8	100
		PIII(M6+D21)	40	40	100	91.2	100
		PIII(M12)	43	42	97.7	87.7	99.9

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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-vaccination dose 1 at Day 21
PI(M6) = Post-vaccination dose 1 at Month 6
PII(D42) = Post-vaccination dose 2 at Day 42
PII(M6) = Post-vaccination dose 2 at Month 6
PII(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M12)= Post-vaccination dose 2 at Month 12
PIII(M12) = Post-vaccination dose 3 at Month 12

Secondary Outcome Variable(s): Booster SCR of neutralizing antibody titers against the A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains at Month 12 for adults who received the booster dose at Month 6 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Pre-vaccination status**	**N**	**Booster SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Vietnam	VT/IN/6	S-	14	14	100	76.8	100
		S+	33	32	97.0	84.2	99.9
		Total	47	46	97.9	88.7	99.9
	VT/VT/6	S-	6	6	100	54.1	100
		S+	36	33	91.7	77.5	98.2
		Total	42	39	92.9	80.5	98.5
	2VT/IN/6	S-	1	1	100	2.5	100
		S+	45	32	71.1	55.7	83.6
		Total	46	33	71.7	56.5	84.0
	2VT/VT/6	S-	0	0	.	.	.
		S+	43	36	83.7	69.3	93.2
		Total	43	36	83.7	69.3	93.2
A/Indonesia	VT/IN/6	S-	31	31	100	88.8	100
		S+	16	16	100	79.4	100
		Total	47	47	100	92.5	100
	VT/VT/6	S-	24	24	100	85.8	100
		S+	18	16	88.9	65.3	98.6
		Total	42	40	95.2	83.8	99.4
	2VT/IN/6	S-	14	14	100	76.8	100
		S+	32	30	93.8	79.2	99.2

		Total	46	44	95.7	85.2	99.5
	2VT/VT/6	S-	20	19	95.0	75.1	99.9
		S+	23	22	95.7	78.1	99.9
		Total	43	41	95.3	84.2	99.4

S- = seronegative subjects (antibody titer < 1:28 for FLU A/VIET/04 AB, FLU A/IND/05 AB) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 1:28 for FLU A/VIET/04 AB, FLU A/IND/05 AB) prior to vaccination
Total = subjects either seropositive or seronegative at pre-vaccination
Booster response defined as :
For initially seronegative subjects, antibody titer ≥ 1:56 at PI(M12) OR PII(M12) OR PIII(M12)
For initially seropositive subjects : antibody titer at PI(M12) OR PII(M12) OR PIII(M12) ≥ 4 fold the pre-vaccination antibody titer
N = number of subjects with both pre- and post-vaccination results available
n/% = number/percentage of responders
95% CI = exact 95% confidence interval; LL = lower limit, UL = upper limit

Secondary Outcome Variable(s): Booster SCR of neutralizing antibody titers against A/Vietnam/1194/2004 or A/Indonesia/05/2005 strains up to Month 12 + 21 Days, for adults who received the booster dose at Month 12 – Pre-booster time point as Month 12 (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	Booster SCR			
				n	%	95% CI	
						LL	UL
A/Vietnam	VT/IN/12	PII(M12+D7)	51	17	33.3	20.8	47.9
		PII(M12+D21)	51	31	60.8	46.1	74.2
	VT/VT/12	PII(M12+D7)	49	16	32.7	19.9	47.5
		PII(M12+D21)	50	25	50.0	35.5	64.5
	2VT/IN/12	PIII(M12+D7)	42	18	42.9	27.7	59.0
		PIII(M12+D21)	42	31	73.8	58.0	86.1
	2VT/VT/12	PIII(M12+D7)	40	19	47.5	31.5	63.9
		PIII(M12+D21)	40	21	52.5	36.1	68.5
A/Indonesia	VT/IN/12	PII(M12+D7)	51	42	82.4	69.1	91.6
		PII(M12+D21)	51	46	90.2	78.6	96.7
	VT/VT/12	PII(M12+D7)	49	35	71.4	56.7	83.4
		PII(M12+D21)	50	39	78.0	64.0	88.5
	2VT/IN/12	PIII(M12+D7)	42	34	81.0	65.9	91.4
		PIII(M12+D21)	43	42	97.7	87.7	99.9
	2VT/VT/12	PIII(M12+D7)	40	20	50.0	33.8	66.2
		PIII(M12+D21)	40	29	72.5	56.1	85.4

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
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(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12

Secondary Outcome Variable(s): Booster SCR of neutralizing antibody titers against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 6 + Day 7, Month 6 + Day 21 and Month 18 for adults who received the booster dose at Month 6 – Pre-vaccination time point as Month 6 (ATP cohort for Persistence)

Antibodies against	Group	Timing	N	Booster SCR			
				n	%	95%CI	
						LL	UL
A/Vietnam	VT/IN/6	PII(M6+D7)	48	44	91.7	80.0	97.7
		PII(M6+D21)	47	46	97.9	88.7	99.9
		PII(M18)	44	33	75.0	59.7	86.8
	VT/VT/6	PII(M6+D7)	42	40	95.2	83.8	99.4

		PII(M6+D21)	42	41	97.6	87.4	99.9
		PII(M18)	42	35	83.3	68.6	93.0
	2VT/IN/6	PIII(M6+D7)	45	35	77.8	62.9	88.8
		PIII(M6+D21)	46	39	84.8	71.1	93.7
		PIII(M18)	46	26	56.5	41.1	71.1
	2VT/VT/6	PIII(M6+D7)	42	38	90.5	77.4	97.3
		PIII(M6+D21)	41	40	97.6	87.1	99.9
		PIII(M18)	40	27	67.5	50.9	81.4
A/Indonesia	VT/IN/6	PII(M6+D7)	48	48	100	92.6	100
		PII(M6+D21)	46	46	100	92.3	100
		PII(M18)	44	40	90.9	78.3	97.5
	VT/VT/6	PII(M6+D7)	42	41	97.6	87.4	99.9
		PII(M6+D21)	42	41	97.6	87.4	99.9
		PII(M18)	42	32	76.2	60.5	87.9
	2VT/IN/6	PIII(M6+D7)	45	43	95.6	84.9	99.5
		PIII(M6+D21)	46	45	97.8	88.5	99.9
		PIII(M18)	46	38	82.6	68.6	92.2
	2VT/VT/6	PIII(M6+D7)	42	41	97.6	87.4	99.9
		PIII(M6+D21)	39	39	100	91.0	100
		PIII(M18)	40	32	80.0	64.4	90.9

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after booster (Month 6)
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold after booster (Month 6) antibody titer
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(M6+D7) = Post-vaccination dose 2 at Day 7 after Month 6
PII(M6+D21) = Post-vaccination dose 2 at Day 21 after Month 6
PIII(M6+D7) = Post-vaccination dose 3 at Day 7 after Month 6
PIII(M6+D21) = Post-vaccination dose 3 at Day 21 after Month 6
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): Booster SCR of neutralizing antibody titers against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 12 + Day 7, Month 12 + Day 21 and Month 18 for adults who received the booster dose at Month 12 – Pre-vaccination time point as Month 12 (ATP cohort for Persistence)

Antibodies against	**Group**	**Timing**	**N**	**Booster SCR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/Vietnam	VT/IN/12	PII(M12+D7)	47	15	31.9	19.1	47.1
		PII(M12+D21)	47	30	63.8	48.5	77.3
		PII(M18)	44	8	18.2	8.2	32.7
	VT/VT/12	PII(M12+D7)	47	15	31.9	19.1	47.1
		PII(M12+D21)	48	23	47.9	33.3	62.8
		PII(M18)	47	7	14.9	6.2	28.3
	2VT/IN/12	PIII(M12+D7)	39	17	43.6	27.8	60.4
		PIII(M12+D21)	39	29	74.4	57.9	87.0
		PIII(M18)	38	16	42.1	26.3	59.2
	2VT/VT/12	PIII(M12+D7)	40	19	47.5	31.5	63.9
		PIII(M12+D21)	40	21	52.5	36.1	68.5
		PIII(M18)	40	10	25.0	12.7	41.2
A/Indonesia	VT/IN/12	PII(M12+D7)	47	39	83.0	69.2	92.4
		PII(M12+D21)	47	44	93.6	82.5	98.7
		PII(M18)	44	33	75.0	59.7	86.8
	VT/VT/12	PII(M12+D7)	47	34	72.3	57.4	84.4
		PII(M12+D21)	48	38	79.2	65.0	89.5
		PII(M18)	47	25	53.2	38.1	67.9

	2VT/IN/12	PIII(M12+D7)	39	32	82.1	66.5	92.5
		PIII(M12+D21)	40	39	97.5	86.8	99.9
		PIII(M18)	39	31	79.5	63.5	90.7
	2VT/VT/12	PIII(M12+D7)	40	20	50.0	33.8	66.2
		PIII(M12+D21)	40	29	72.5	56.1	85.4
		PIII(M18)	40	18	45.0	29.3	61.5

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after booster (Month 12) vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the after booster (Month 12) antibody titer
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(M12+D7) = Post-vaccination dose 2 at Day 7 after Month 12
PII(M12+D21) = Post-vaccination dose 2 at Day 21 after Month 12
PIII(M12+D7) = Post-vaccination dose 3 at Day 7 after Month 12
PIII(M12+D21) = Post-vaccination dose 3 at Day 21 after Month 12
PII(M18) = Post-vaccination dose 2 at Month 18
PIII(M18) = Post-vaccination dose 3 at Month 18

Secondary Outcome Variable(s): Descriptive Statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD4 ALL DOUBLES, CD4 CD40L, CD4 IL-2, CD4 IFN-gamma, CD4 TNF-alpha for the Month 6 booster group (ATP cohort for immunogenicity)

Test description	Stimulating antigen	Group	Timing	N	GM	SD
CD4 ALL DOUBLES	A/Vietnam	VT/IN/6	PRE	41	412.03	487.53
			PI(M6)	30	600.07	901.78
			PII(M6+D7)	29	1120.95	2182.54
			PII(M6+D21)	32	1619.46	1899.48
		VT/VT/6	PRE	42	467.30	333.87
			PI(M6)	32	807.14	806.63
			PII(M6+D7)	26	1369.15	1224.75
			PII(M6+D21)	30	1531.69	1741.38
		2VT/IN/6	PRE	36	395.60	477.64
			PII(M6)	32	896.67	627.38
			PIII(M6+D7)	21	1914.50	1757.90
			PIII(M6+D21)	25	1489.30	1564.28
		2VT/VT/6	PRE	35	469.25	470.89
			PII(M6)	27	1071.19	923.45
			PIII(M6+D7)	22	1769.33	1024.50
			PIII(M6+D21)	31	1953.30	2219.16
CD4 CD40L	A/Vietnam	VT/IN/6	PRE	41	350.86	455.52
			PI(M6)	30	593.74	885.01
			PII(M6+D7)	29	1084.46	2123.12
			PII(M6+D21)	32	1588.60	1855.12
		VT/VT/6	PRE	42	446.27	318.18
			PI(M6)	32	809.47	777.20
			PII(M6+D7)	26	1298.95	1153.28
			PII(M6+D21)	30	1487.73	1663.98
		2VT/IN/6	PRE	36	387.68	458.40
			PII(M6)	32	867.92	591.04
			PIII(M6+D7)	21	1818.39	1603.64
			PIII(M6+D21)	25	1480.21	1520.92
		2VT/VT/6	PRE	35	441.16	460.09
			PII(M6)	27	1046.99	893.54
			PIII(M6+D7)	22	1717.69	990.51
			PIII(M6+D21)	31	1880.07	2151.87
CD4 IL-2	A/Vietnam	VT/IN/6	PRE	41	262.64	339.55
			PI(M6)	30	450.20	815.29

			PII(M6+D7)	29	861.32	1997.52
			PII(M6+D21)	32	1238.06	1759.16
		VT/VT/6	PRE	42	264.51	249.40
			PI(M6)	32	601.02	736.05
			PII(M6+D7)	26	890.90	1030.87
			PII(M6+D21)	30	1036.73	1545.30
		2VT/IN/6	PRE	36	230.40	360.46
			PII(M6)	32	648.07	584.83
			PIII(M6+D7)	21	1390.30	1480.20
			PIII(M6+D21)	25	965.41	1302.89
		2VT/VT/6	PRE	35	289.83	385.44
			PII(M6)	27	719.07	763.89
			PIII(M6+D7)	22	1147.31	980.42
			PIII(M6+D21)	31	1380.65	1761.07
CD4 IFN-γ	A/Vietnam	VT/IN/6	PRE	41	303.97	403.90
			PI(M6)	30	309.94	596.66
			PII(M6+D7)	29	632.73	848.00
			PII(M6+D21)	32	769.33	858.31
		VT/VT/6	PRE	42	267.88	316.20
			PI(M6)	32	486.23	524.58
			PII(M6+D7)	26	683.35	702.66
			PII(M6+D21)	30	831.31	964.67
		2VT/IN/6	PRE	36	275.09	299.79
			PII(M6)	32	406.50	364.57
			PIII(M6+D7)	21	826.27	856.63
			PIII(M6+D21)	25	712.10	806.47
		2VT/VT/6	PRE	35	331.35	379.46
			PII(M6)	27	543.11	607.67
			PIII(M6+D7)	22	887.74	412.30
			PIII(M6+D21)	31	908.75	952.74
CD4 TNF-α	A/Vietnam	VT/IN/6	PRE	41	213.17	314.89
			PI(M6)	30	389.55	823.34
			PII(M6+D7)	29	605.80	1282.37
			PII(M6+D21)	32	880.12	1327.15
		VT/VT/6	PRE	42	290.55	244.57
			PI(M6)	32	459.89	709.54
			PII(M6+D7)	26	700.69	893.07
			PII(M6+D21)	30	971.44	1419.68
		2VT/IN/6	PRE	36	248.53	334.40
			PII(M6)	32	501.89	496.82
			PIII(M6+D7)	21	1160.60	1524.45
			PIII(M6+D21)	25	881.65	1218.69
		2VT/VT/6	PRE	35	262.12	309.11
			PII(M6)	27	684.19	700.61
			PIII(M6+D7)	22	972.71	668.12
			PIII(M6+D21)	31	1227.63	1871.42

N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine

Secondary Outcome Variable(s): Descriptive Statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD4 ALL DOUBLES, CD4 CD40L, CD4 IL-2, CD4 IFN-gamma, CD4 TNF-alpha for subjects who received the booster dose at Month 12 (ATP cohort for immunogenicity)

Test description	Stimulating antigen	Group	Timing	N	GM	SD
CD4 ALL DOUBLES	A/Vietnam	VT/IN/12	PRE	47	560.41	427.07
			PI(M6)	32	1296.63	839.72
		VT/VT/12	PRE	51	529.20	549.34
			PI(M6)	31	931.49	717.72
		2VT/IN/12	PRE	46	542.86	488.28
			PII(M6)	36	1714.23	837.39
		2VT/VT/12	PRE	43	771.60	788.54
			PII(M6)	28	1601.31	1020.97
CD4 CD40L	A/Vietnam	VT/IN/12	PRE	47	536.99	406.96
			PI(M6)	32	1272.27	819.74
		VT/VT/12	PRE	51	505.20	497.95
			PI(M6)	31	891.65	657.93
		2VT/IN/12	PRE	46	504.23	476.25
			PII(M6)	36	1659.46	823.79
		2VT/VT/12	PRE	43	729.16	736.68
			PII(M6)	28	1548.04	918.09
CD4 IL-2	A/Vietnam	VT/IN/12	PRE	47	376.07	336.28
			PI(M6)	32	1097.97	712.55
		VT/VT/12	PRE	51	409.33	480.49
			PI(M6)	31	804.03	632.15
		2VT/IN/12	PRE	46	436.65	411.16
			PII(M6)	36	1461.85	769.17
		2VT/VT/12	PRE	43	612.11	632.55
			PII(M6)	28	1403.84	915.32
CD4 IFN-γ	A/Vietnam	VT/IN/12	PRE	47	410.28	363.50
			PI(M6)	32	690.45	600.77
		VT/VT/12	PRE	51	336.74	443.20
			PI(M6)	31	539.79	432.94
		2VT/IN/12	PRE	46	379.98	364.14
			PII(M6)	36	771.40	459.71
		2VT/VT/12	PRE	43	476.66	687.60
			PII(M6)	28	748.72	758.34
CD4 TNF-α	A/Vietnam	VT/IN/12	PRE	47	355.17	302.08
			PI(M6)	32	886.97	662.75
		VT/VT/12	PRE	51	287.10	423.56
			PI(M6)	31	629.87	556.20
		2VT/IN/12	PRE	46	341.11	356.99
			PII(M6)	36	1187.24	710.18
		2VT/VT/12	PRE	43	512.64	572.95
			PII(M6)	28	1180.29	829.76

N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine

Secondary Outcome Variable(s): Descriptive Statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD8 ALL DOUBLES, CD8 CD40L, CD8 IL-2, CD8 IFN-gamma, CD8 TNF-alpha for the Month 6 booster group (ATP cohort for immunogenicity)

Test description	Stimulating antigen	Group	Timing	N	GM	SD
CD8 ALL DOUBLES	A/Vietnam	VT/IN/6	PRE	41	67.13	366.43
			PI(M6)	29	20.86	222.56
			PII(M6+D7)	29	23.01	290.71
			PII(M6+D21)	31	29.21	281.87

		VT/VT/6	PRE	40	26.91	128.98
			PI(M6)	31	18.86	271.65
			PII(M6+D7)	25	27.73	93.80
			PII(M6+D21)	28	52.59	159.49
		2VT/IN/6	PRE	36	30.44	219.02
			PII(M6)	32	37.69	271.61
			PIII(M6+D7)	21	38.78	211.71
			PIII(M6+D21)	25	36.47	171.22
		2VT/VT/6	PRE	34	45.07	377.44
			PII(M6)	27	40.43	148.42
			PIII(M6+D7)	22	32.56	150.48
			PIII(M6+D21)	31	16.93	105.56
CD8 CD40L	A/Vietnam	VT/IN/6	PRE	41	7.17	84.29
			PI(M6)	29	3.12	35.61
			PII(M6+D7)	29	6.26	71.82
			PII(M6+D21)	31	2.11	22.77
		VT/VT/6	PRE	40	4.74	71.68
			PI(M6)	31	7.18	39.67
			PII(M6+D7)	25	3.55	30.06
			PII(M6+D21)	28	4.88	37.26
		2VT/IN/6	PRE	36	5.49	39.03
			PII(M6)	32	5.01	69.22
			PIII(M6+D7)	21	6.28	34.99
			PIII(M6+D21)	25	3.78	33.23
		2VT/VT/6	PRE	34	6.15	165.75
			PII(M6)	27	4.81	49.19
			PIII(M6+D7)	22	5.92	45.82
			PIII(M6+D21)	31	3.21	30.61
CD8 IL-2	A/Vietnam	VT/IN/6	PRE	41	36.92	229.00
			PI(M6)	29	12.84	129.21
			PII(M6+D7)	29	16.03	218.16
			PII(M6+D21)	31	31.00	185.96
		VT/VT/6	PRE	40	14.67	100.62
			PI(M6)	31	12.58	239.74
			PII(M6+D7)	25	17.04	92.98
			PII(M6+D21)	28	28.04	156.16
		2VT/IN/6	PRE	36	16.98	130.69
			PII(M6)	32	22.68	113.81
			PIII(M6+D7)	21	32.94	154.53
			PIII(M6+D21)	25	22.75	138.13
		2VT/VT/6	PRE	34	27.00	258.14
			PII(M6)	27	25.91	102.37
			PIII(M6+D7)	22	26.46	113.81
			PIII(M6+D21)	31	13.48	93.72
CD8 IFN-γ	A/Vietnam	VT/IN/6	PRE	41	29.70	347.16
			PI(M6)	29	9.15	195.76
			PII(M6+D7)	29	17.52	252.30
			PII(M6+D21)	31	9.86	272.26
		VT/VT/6	PRE	40	14.50	125.14
			PI(M6)	31	15.10	164.89
			PII(M6+D7)	25	6.54	65.11
			PII(M6+D21)	28	16.87	111.49
		2VT/IN/6	PRE	36	24.17	183.45
			PII(M6)	32	25.09	269.60
			PIII(M6+D7)	21	6.15	190.69
			PIII(M6+D21)	25	15.44	132.81

		2VT/VT/6	PRE	34	23.68	347.01
			PII(M6)	27	10.92	133.43
			PIII(M6+D7)	22	12.90	96.83
			PIII(M6+D21)	31	11.37	82.16
CD8 TNF-α	A/Vietnam	VT/IN/6	PRE	41	25.46	308.45
			PI(M6)	29	11.60	192.99
			PII(M6+D7)	29	17.12	200.81
			PII(M6+D21)	31	28.56	229.92
		VT/VT/6	PRE	40	14.67	92.23
			PI(M6)	31	17.44	260.42
			PII(M6+D7)	25	14.74	90.05
			PII(M6+D21)	28	38.71	137.20
		2VT/IN/6	PRE	36	22.21	183.41
			PII(M6)	32	21.86	254.39
			PIII(M6+D7)	21	25.85	186.72
			PIII(M6+D21)	25	27.86	156.35
		2VT/VT/6	PRE	34	35.35	219.77
			PII(M6)	27	20.44	140.65
			PIII(M6+D7)	22	27.99	151.32
			PIII(M6+D21)	31	11.99	83.27

N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
CD8-CD40L: CD8 T-cells producing at least CD40L and another cytokine
CD8-IL-2: CD8 T-cells producing at least IL2 and another cytokine
CD8-INFγ: CD8 T-cells producing at least INF gamma and another cytokine
CD8-TNFα: CD8 T-cells producing at least TNF alpha and another cytokine

Secondary Outcome Variable(s): Descriptive Statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD8 ALL DOUBLES, CD8 CD40L, CD8 IL-2, CD8 IFN-gamma, CD8 TNF-alpha for subjects who received the booster dose at Month 12 (ATP cohort for immunogenicity)

Test description	**Stimulating antigen**	**Group**	**Timing**	**N**	**GM**	**SD**
CD8 ALL DOUBLES	A/Vietnam	VT/IN/12	PRE	47	33.23	473.07
			PI(M6)	32	56.22	359.78
		VT/VT/12	PRE	49	30.79	332.90
			PI(M6)	31	60.15	348.65
		2VT/IN/12	PRE	46	18.67	297.54
			PII(M6)	36	31.83	296.96
		2VT/VT/12	PRE	43	21.71	163.41
			PII(M6)	28	34.66	208.62
CD8 CD40L	A/Vietnam	VT/IN/12	PRE	47	3.05	54.73
			PI(M6)	32	2.59	24.33
		VT/VT/12	PRE	49	3.22	55.84
			PI(M6)	31	3.07	55.80
		2VT/IN/12	PRE	46	2.48	130.89
			PII(M6)	36	3.00	101.52
		2VT/VT/12	PRE	43	2.79	19.72
			PII(M6)	28	1.51	20.14
CD8 IL-2	A/Vietnam	VT/IN/12	PRE	47	18.34	169.79
			PI(M6)	32	24.13	246.71
		VT/VT/12	PRE	49	22.25	202.40
			PI(M6)	31	30.85	186.03
		2VT/IN/12	PRE	46	10.40	167.00
			PII(M6)	36	16.53	173.90
		2VT/VT/12	PRE	43	15.03	86.58
			PII(M6)	28	19.63	145.48
CD8 IFN-γ	A/Vietnam	VT/IN/12	PRE	47	38.69	468.52

			PI(M6)	32	31.09	359.03
		VT/VT/12	PRE	49	22.01	312.45
			PI(M6)	31	42.77	334.23
		2VT/IN/12	PRE	46	16.63	273.01
			PII(M6)	36	24.28	290.45
		2VT/VT/12	PRE	43	24.90	165.67
			PII(M6)	28	30.08	200.12
CD8 TNF-α	A/Vietnam	VT/IN/12	PRE	47	24.58	437.31
			PI(M6)	32	31.78	296.04
		VT/VT/12	PRE	49	19.36	258.56
			PI(M6)	31	25.01	272.87
		2VT/IN/12	PRE	46	11.36	179.18
			PII(M6)	36	26.33	205.26
		2VT/VT/12	PRE	43	14.50	136.30
			PII(M6)	28	30.46	172.62

N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
CD8-CD40L: CD8 T-cells producing at least CD40L and another cytokine
CD8-IL-2: CD8 T-cells producing at least IL2 and another cytokine
CD8-INFγ: CD8 T-cells producing at least INF gamma and another cytokine
CD8-TNFα: CD8 T-cells producing at least TNF alpha and another cytokine

Secondary Outcome Variable(s): Descriptive statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD4 ALL DOUBLES, CD4 CD40L, CD4 IL-2, CD4 IFN-γ, CD4 TNF-α – at Month 12 and Month 18 for subjects boosted at Month 6 (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	SD
CD4 ALL DOUBLES	A/Indonesia	VT/IN/6	PII(M12)	33	1196.05	1279.60
			PII(M18)	37	1192.82	1000.13
		VT/VT/6	PII(M12)	33	1461.46	1972.69
			PII(M18)	36	1767.82	1194.85
		2VT/IN/6	PIII(M12)	35	1512.82	996.79
			PIII(M18)	33	1978.73	1138.17
		2VT/VT/6	PIII(M12)	31	1243.41	1434.39
			PIII(M18)	34	1550.40	1557.30
	A/Vietnam	VT/IN/6	PII(M12)	33	1316.68	1359.39
			PII(M18)	37	1194.69	1073.65
		VT/VT/6	PII(M12)	33	1431.92	1291.80
			PII(M18)	36	1790.56	1178.39
		2VT/IN/6	PIII(M12)	35	1506.94	1086.61
			PIII(M18)	33	1676.20	1267.85
		2VT/VT/6	PIII(M12)	31	1220.87	2280.45
			PIII(M18)	34	1560.54	1546.70
CD4 CD40L	A/Indonesia	VT/IN/6	PII(M12)	33	1183.85	1255.59
			PII(M18)	37	1172.36	985.13
		VT/VT/6	PII(M12)	33	1448.44	1973.98
			PII(M18)	36	1747.96	1151.98
		2VT/IN/6	PIII(M12)	35	1505.73	985.99
			PIII(M18)	33	1975.69	1126.07
		2VT/VT/6	PIII(M12)	31	1221.20	1371.18
			PIII(M18)	34	1522.12	1553.48
	A/Vietnam	VT/IN/6	PII(M12)	33	1238.24	1362.58
			PII(M18)	37	1162.79	1043.15
		VT/VT/6	PII(M12)	33	1390.02	1288.92
			PII(M18)	36	1738.30	1140.59
		2VT/IN/6	PIII(M12)	35	1474.26	1073.10
			PIII(M18)	33	1640.12	1252.01

		2VT/VT/6	PIII(M12)	31	1152.29	2263.92
			PIII(M18)	34	1518.75	1489.22
CD4 IL-2	A/Indonesia	VT/IN/6	PII(M12)	33	1001.88	1156.16
			PII(M18)	37	999.22	844.48
		VT/VT/6	PII(M12)	33	1169.25	1630.99
			PII(M18)	36	1412.43	986.25
		2VT/IN/6	PIII(M12)	35	1278.49	908.04
			PIII(M18)	33	1480.68	1040.08
		2VT/VT/6	PIII(M12)	31	1041.21	1250.37
			PIII(M18)	34	1248.66	1383.46
	A/Vietnam	VT/IN/6	PII(M12)	33	1119.56	1261.18
			PII(M18)	37	1011.14	921.27
		VT/VT/6	PII(M12)	33	1160.06	1049.95
			PII(M18)	36	1487.16	1006.20
		2VT/IN/6	PIII(M12)	35	1264.64	1008.46
			PIII(M18)	33	1434.59	1156.89
		2VT/VT/6	PIII(M12)	31	999.23	2005.29
			PIII(M18)	34	1140.29	1374.45
CD4 INF-γ	A/Indonesia	VT/IN/6	PII(M12)	33	615.47	624.58
			PII(M18)	37	657.19	622.98
		VT/VT/6	PII(M12)	33	829.05	903.32
			PII(M18)	36	972.81	1026.12
		2VT/IN/6	PIII(M12)	35	752.50	525.81
			PIII(M18)	33	1017.82	655.54
		2VT/VT/6	PIII(M12)	31	746.33	727.94
			PIII(M18)	34	883.75	969.20
	A/Vietnam	VT/IN/6	PII(M12)	33	751.16	604.70
			PII(M18)	37	698.55	804.64
		VT/VT/6	PII(M12)	33	851.71	727.68
			PII(M18)	36	1018.23	959.34
		2VT/IN/6	PIII(M12)	35	817.48	568.54
			PIII(M18)	33	1066.89	845.76
		2VT/VT/6	PIII(M12)	31	832.49	1138.08
			PIII(M18)	34	949.06	949.59
CD4 TNF-α	A/Indonesia	VT/IN/6	PII(M12)	33	914.94	1053.34
			PII(M18)	37	922.42	794.83
		VT/VT/6	PII(M12)	33	1125.16	1559.54
			PII(M18)	36	1318.59	923.86
		2VT/IN/6	PIII(M12)	35	1235.28	813.44
			PIII(M18)	33	1647.61	927.11
		2VT/VT/6	PIII(M12)	31	1148.53	1208.96
			PIII(M18)	34	1224.50	1267.20
	A/Vietnam	VT/IN/6	PII(M12)	33	970.90	1091.23
			PII(M18)	37	877.90	810.80
		VT/VT/6	PII(M12)	33	1047.93	978.11
			PII(M18)	36	1314.99	846.99
		2VT/IN/6	PIII(M12)	35	1238.05	858.40
			PIII(M18)	33	1232.41	1079.43
		2VT/VT/6	PIII(M12)	31	1096.87	1906.75
			PIII(M18)	34	1147.21	1402.58

N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine

CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine

Secondary Outcome Variable(s): Descriptive statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD8 ALL DOUBLES, CD8 CD40l, CD8 IL-2, CD8 IFN-γ and CD8 TNF-α at Month 12 and Month 18 for subjects boosted at Month 6 (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	SD
CD8 ALL DOUBLES	A/Indonesia	VT/IN/6	PII(M12)	32	47.78	1206.89
			PII(M18)	37	48.27	1109.56
		VT/VT/6	PII(M12)	32	31.69	1136.66
			PII(M18)	35	24.19	1162.30
		2VT/IN/6	PIII(M12)	35	64.08	1893.94
			PIII(M18)	33	82.90	1266.82
		2VT/VT/6	PIII(M12)	31	36.18	1567.28
			PIII(M18)	33	34.07	1414.34
	A/Vietnam	VT/IN/6	PII(M12)	31	15.04	544.79
			PII(M18)	36	33.20	623.81
		VT/VT/6	PII(M12)	32	21.08	635.65
			PII(M18)	35	12.14	907.62
		2VT/IN/6	PIII(M12)	35	37.32	744.75
			PIII(M18)	33	29.83	673.80
		2VT/VT/6	PIII(M12)	29	14.09	771.65
			PIII(M18)	32	11.17	676.65
CD8 CD40L	A/Indonesia	VT/IN/6	PII(M12)	32	3.92	58.33
			PII(M18)	37	5.88	71.14
		VT/VT/6	PII(M12)	32	5.74	93.30
			PII(M18)	35	5.23	269.38
		2VT/IN/6	PIII(M12)	35	9.05	186.92
			PIII(M18)	33	5.25	71.46
		2VT/VT/6	PIII(M12)	31	7.74	144.04
			PIII(M18)	33	3.66	56.08
	A/Vietnam	VT/IN/6	PII(M12)	31	2.27	33.81
			PII(M18)	36	5.71	53.55
		VT/VT/6	PII(M12)	32	3.40	67.73
			PII(M18)	35	2.75	96.74
		2VT/IN/6	PIII(M12)	35	5.10	65.14
			PIII(M18)	33	4.14	95.17
		2VT/VT/6	PIII(M12)	29	3.35	47.52
			PIII(M18)	32	3.07	40.00
CD8 IL-2	A/Indonesia	VT/IN/6	PII(M12)	32	40.26	1211.36
			PII(M18)	37	43.26	1110.98
		VT/VT/6	PII(M12)	32	27.79	1135.75
			PII(M18)	35	19.50	1164.40
		2VT/IN/6	PIII(M12)	35	48.91	1897.48
			PIII(M18)	33	66.29	1268.66
		2VT/VT/6	PIII(M12)	31	28.61	1566.57
			PIII(M18)	33	33.60	1414.79
	A/Vietnam	VT/IN/6	PII(M12)	31	14.98	532.13
			PII(M18)	36	32.16	615.73
		VT/VT/6	PII(M12)	32	21.52	631.86
			PII(M18)	35	11.75	902.78
		2VT/IN/6	PIII(M12)	35	31.94	746.85
			PIII(M18)	33	26.63	674.63
		2VT/VT/6	PIII(M12)	29	13.31	773.02
			PIII(M18)	32	9.50	678.33
CD8 INF-γ	A/Indonesia	VT/IN/6	PII(M12)	32	3.05	131.52
			PII(M18)	37	4.74	91.61
		VT/VT/6	PII(M12)	32	4.05	147.20

			PII(M18)	35	4.33	111.98
		2VT/IN/6	PIII(M12)	35	4.11	75.97
			PIII(M18)	33	4.61	83.81
		2VT/VT/6	PIII(M12)	31	2.83	38.52
			PIII(M18)	33	3.73	97.93
	A/Vietnam	VT/IN/6	PII(M12)	31	4.44	305.15
			PII(M18)	36	5.73	64.14
		VT/VT/6	PII(M12)	32	4.24	133.39
			PII(M18)	35	3.55	138.59
		2VT/IN/6	PIII(M12)	35	10.21	83.42
			PIII(M18)	33	5.22	95.47
		2VT/VT/6	PIII(M12)	29	4.42	56.81
			PIII(M18)	32	3.15	107.32
CD8 TNF-α	A/Indonesia	VT/IN/6	PII(M12)	32	46.49	1154.66
			PII(M18)	37	45.67	1033.79
		VT/VT/6	PII(M12)	32	27.72	1030.52
			PII(M18)	35	22.55	1002.19
		2VT/IN/6	PIII(M12)	35	57.62	1753.76
			PIII(M18)	33	70.09	1200.29
		2VT/VT/6	PIII(M12)	31	31.65	1425.49
			PIII(M18)	33	34.37	1369.22
	A/Vietnam	VT/IN/6	PII(M12)	31	13.46	423.36
			PII(M18)	36	31.41	580.62
		VT/VT/6	PII(M12)	32	18.89	579.22
			PII(M18)	35	12.96	816.63
		2VT/IN/6	PIII(M12)	35	35.19	698.32
			PIII(M18)	33	21.36	614.44
		2VT/VT/6	PIII(M12)	29	12.30	725.71
			PIII(M18)	32	9.31	642.97

N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
CD8-CD40L: CD8 T-cells producing at least CD40L and another cytokine
CD8-IL-2: CD8 T-cells producing at least IL2 and another cytokine
CD8-INFγ: CD8 T-cells producing at least INF gamma and another cytokine
CD8-TNFα: CD8 T-cells producing at least TNF alpha and another cytokine

Secondary Outcome Variable(s): Descriptive statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD4 ALL DOUBLES, CD4 CD40L, CD4 IL-2, CD4 IFN- and CD4 TNF- *at Month 12, Month 12+7 Days, Month 12+21 Days and Month 18 for subjects boosted at Month 12* (ATP cohort for immunogenicity)

Test description	**Stimulating antigen**	**Group**	**Timing**	**N**	**GM**	**SD**
CD4 ALL DOUBLES	A/Indonesia	VT/IN/12	PI(M12)	33	1379.04	701.03
			PII(M12+D7)	38	1979.02	1644.97
			PII(M12+D21)	37	2837.94	1587.84
			PII(M18)	39	2003.28	964.77
		VT/VT/12	PI(M12)	34	1254.05	835.74
			PII(M12+D7)	39	1763.05	1266.55
			PII(M12+D21)	38	2180.14	2032.36
			PII(M18)	38	1530.61	1228.44
		2VT/IN/12	PII(M12)	23	1690.38	1135.04
			PIII(M12+D7)	26	3030.85	1974.08
			PIII(M12+D21)	30	3600.62	2903.90
			PIII(M18)	27	2975.66	1696.72
		2VT/VT/12	PII(M12)	31	1534.37	1256.20
			PIII(M12+D7)	32	3202.67	7114.42
			PIII(M12+D21)	32	3221.46	2824.65
			PIII(M18)	30	2458.61	1829.69

	A/Vietnam	VT/IN/12	PI(M12)	29	1230.51	523.55
			PII(M12+D7)	41	2278.65	2822.40
			PII(M12+D21)	38	2651.19	2181.61
			PII(M18)	42	2230.56	1780.46
		VT/VT/12	PI(M12)	33	1093.54	941.19
			PII(M12+D7)	40	1856.17	1517.33
			PII(M12+D21)	41	2276.18	1434.51
			PII(M18)	43	1628.90	2059.72
		2VT/IN/12	PII(M12)	21	1260.93	1118.44
			PIII(M12+D7)	26	2953.57	2725.45
			PIII(M12+D21)	32	3386.98	3153.08
			PIII(M18)	30	2972.79	1797.59
		2VT/VT/12	PII(M12)	30	1224.35	2953.68
			PIII(M12+D7)	33	3502.70	19908.39
			PIII(M12+D21)	32	3603.01	3804.83
			PIII(M18)	32	2535.97	2627.53
CD4 CD40L	A/Indonesia	VT/IN/12	PI(M12)	33	1361.91	670.66
			PII(M12+D7)	38	1968.90	1594.19
			PII(M12+D21)	37	2744.31	1545.16
			PII(M18)	39	1943.30	922.92
		VT/VT/12	PI(M12)	34	1209.07	715.01
			PII(M12+D7)	39	1724.77	1242.19
			PII(M12+D21)	38	2097.74	1860.85
			PII(M18)	38	1532.05	1186.69
		2VT/IN/12	PII(M12)	23	1610.40	1079.91
			PIII(M12+D7)	26	2880.43	1936.74
			PIII(M12+D21)	30	3431.78	2897.09
			PIII(M18)	27	2859.97	1657.11
		2VT/VT/12	PII(M12)	31	1478.55	1259.28
			PIII(M12+D7)	32	3101.88	6940.95
			PIII(M12+D21)	32	3124.45	2787.90
			PIII(M18)	30	2317.11	1865.51
	A/Vietnam	VT/IN/12	PI(M12)	29	1189.38	519.31
			PII(M12+D7)	41	2179.65	2615.03
			PII(M12+D21)	38	2583.09	2102.23
			PII(M18)	42	2174.81	1734.47
		VT/VT/12	PI(M12)	33	1059.77	917.49
			PII(M12+D7)	40	1781.72	1287.53
			PII(M12+D21)	41	2184.58	1371.47
			PII(M18)	43	1755.83	1930.06
		2VT/IN/12	PII(M12)	21	1217.48	1056.53
			PIII(M12+D7)	26	2842.20	2607.80
			PIII(M12+D21)	32	3179.78	3132.51
			PIII(M18)	30	2849.08	1755.65
		2VT/VT/12	PII(M12)	30	1173.39	2904.15
			PIII(M12+D7)	33	3365.20	18999.95
			PIII(M12+D21)	32	3479.95	3622.29
			PIII(M18)	32	2483.47	2583.46
CD4 IL-2	A/Indonesia	VT/IN/12	PI(M12)	33	1149.50	571.65
			PII(M12+D7)	38	1498.36	1396.73
			PII(M12+D21)	37	2392.88	1398.76
			PII(M18)	39	1703.60	838.53
		VT/VT/12	PI(M12)	34	1065.33	661.19
			PII(M12+D7)	39	1476.33	1015.37
			PII(M12+D21)	38	1858.04	1721.69
			PII(M18)	38	1383.29	1077.39

		2VT/IN/12	PII(M12)	23	1517.94	1028.90
			PIII(M12+D7)	26	2543.33	1712.80
			PIII(M12+D21)	30	3108.60	2632.60
			PIII(M18)	27	2559.41	1683.14
		2VT/VT/12	PII(M12)	31	1293.00	1103.73
			PIII(M12+D7)	32	2670.96	5571.66
			PIII(M12+D21)	32	2747.73	2516.72
			PIII(M18)	30	2104.29	1607.98
	A/Vietnam	VT/IN/12	PI(M12)	29	992.70	427.17
			PII(M12+D7)	41	1897.17	2415.04
			PII(M12+D21)	38	2268.27	1995.17
			PII(M18)	42	1869.31	1525.68
		VT/VT/12	PI(M12)	33	814.08	714.13
			PII(M12+D7)	40	1533.21	1397.88
			PII(M12+D21)	41	1932.19	1276.22
			PII(M18)	43	1394.95	1933.81
		2VT/IN/12	PII(M12)	21	1083.65	1008.19
			PIII(M12+D7)	26	2477.58	2347.38
			PIII(M12+D21)	32	2992.35	2869.19
			PIII(M18)	30	2589.97	1776.18
		2VT/VT/12	PII(M12)	30	1048.97	2636.29
			PIII(M12+D7)	33	2942.81	17299.39
			PIII(M12+D21)	32	3105.21	3366.65
			PIII(M18)	32	2162.08	2461.02
CD4 INF-γ	A/Indonesia	VT/IN/12	PI(M12)	33	716.74	400.83
			PII(M12+D7)	38	973.45	756.29
			PII(M12+D21)	37	1245.91	936.91
			PII(M18)	39	1113.27	598.27
		VT/VT/12	PI(M12)	34	609.84	578.82
			PII(M12+D7)	39	812.11	693.80
			PII(M12+D21)	38	948.13	1366.34
			PII(M18)	38	902.31	742.69
		2VT/IN/12	PII(M12)	23	832.27	746.45
			PIII(M12+D7)	26	1308.07	966.01
			PIII(M12+D21)	30	1540.77	1136.61
			PIII(M18)	27	1329.00	814.58
		2VT/VT/12	PII(M12)	31	794.44	765.51
			PIII(M12+D7)	32	1560.86	2907.99
			PIII(M12+D21)	32	1662.38	1310.77
			PIII(M18)	30	1292.88	1081.31
	A/Vietnam	VT/IN/12	PI(M12)	29	729.77	345.26
			PII(M12+D7)	41	1131.19	1352.73
			PII(M12+D21)	38	1278.22	1209.43
			PII(M18)	42	1309.65	1177.92
		VT/VT/12	PI(M12)	33	565.44	574.28
			PII(M12+D7)	40	892.51	905.48
			PII(M12+D21)	41	1074.61	717.53
			PII(M18)	43	901.99	1416.15
		2VT/IN/12	PII(M12)	21	633.07	650.52
			PIII(M12+D7)	26	1335.77	1104.69
			PIII(M12+D21)	32	1539.76	1287.82
			PIII(M18)	30	1418.76	1038.94
		2VT/VT/12	PII(M12)	30	767.14	1198.67
			PIII(M12+D7)	33	1635.21	7167.21
			PIII(M12+D21)	32	1795.04	2122.78
			PIII(M18)	32	1284.53	1281.98

CD4 TNF-α	A/Indonesia	VT/IN/12	PI(M12)	33	1020.53	642.48
			PII(M12+D7)	38	1198.25	1200.42
			PII(M12+D21)	37	2047.96	1439.33
			PII(M18)	39	1461.90	863.23
		VT/VT/12	PI(M12)	34	896.53	690.42
			PII(M12+D7)	39	1217.50	971.57
			PII(M12+D21)	38	1515.97	1751.14
			PII(M18)	38	1009.39	1077.18
		2VT/IN/12	PII(M12)	23	1251.38	970.03
			PIII(M12+D7)	26	2108.88	1380.62
			PIII(M12+D21)	30	2800.66	2480.69
			PIII(M18)	27	2445.88	1505.10
		2VT/VT/12	PII(M12)	31	995.80	1066.30
			PIII(M12+D7)	32	2379.07	5801.63
			PIII(M12+D21)	32	2510.61	2450.88
			PIII(M18)	30	1979.21	1590.60
	A/Vietnam	VT/IN/12	PI(M12)	29	886.76	457.39
			PII(M12+D7)	41	1289.39	2162.71
			PII(M12+D21)	38	1833.81	2015.18
			PII(M18)	42	1499.43	1302.01
		VT/VT/12	PI(M12)	33	673.80	651.52
			PII(M12+D7)	40	1136.90	1164.93
			PII(M12+D21)	41	1428.02	1030.82
			PII(M18)	43	1250.85	1843.92
		2VT/IN/12	PII(M12)	21	790.01	938.28
			PIII(M12+D7)	26	1997.48	1725.20
			PIII(M12+D21)	32	2373.80	2542.38
			PIII(M18)	30	2269.35	1494.81
		2VT/VT/12	PII(M12)	30	903.64	2220.85
			PIII(M12+D7)	33	2466.32	16740.25
			PIII(M12+D21)	32	2571.60	3441.06
			PIII(M18)	32	1914.16	2270.93

N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine

Secondary Outcome Variable(s): Descriptive statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD8 ALL DOUBLES, CD8 CD40L, CD8 IL-2, CD8 IFN- , CD8 TNF- at Month 12, Month 12+7 Days Month 12+21 Days and Month 18 for subjects boosted at Month 12 (ATP cohort for immunogenicity)

Test description	**Stimulating antigen**	**Group**	**Timing**	**N**	**GM**	**SD**
CD8 ALL DOUBLES	A/Indonesia	VT/IN/12	PI(M12)	32	41.20	285.40
			PII(M12+D7)	34	68.32	385.82
			PII(M12+D21)	34	59.21	402.04
			PII(M18)	34	45.87	268.24
		VT/VT/12	PI(M12)	30	19.96	258.08
			PII(M12+D7)	31	48.09	292.33
			PII(M12+D21)	37	22.21	196.85
			PII(M18)	36	36.98	349.38
		2VT/IN/12	PII(M12)	17	33.27	237.99
			PIII(M12+D7)	22	41.66	276.01
			PIII(M12+D21)	27	42.28	213.86
			PIII(M18)	24	29.12	194.72
		2VT/VT/12	PII(M12)	30	34.16	449.53

			PIII(M12+D7)	26	57.43	369.42
			PIII(M12+D21)	31	60.95	301.71
			PIII(M18)	28	36.73	391.36
	A/Vietnam	VT/IN/12	PI(M12)	28	14.72	293.17
			PII(M12+D7)	31	18.73	398.89
			PII(M12+D21)	38	16.35	341.81
			PII(M18)	41	27.14	378.73
		VT/VT/12	PI(M12)	28	13.96	149.10
			PII(M12+D7)	33	23.11	409.70
			PII(M12+D21)	39	10.06	260.79
			PII(M18)	39	17.52	231.65
		2VT/IN/12	PII(M12)	17	8.90	107.93
			PIII(M12+D7)	23	9.04	325.93
			PIII(M12+D21)	28	16.58	227.02
			PIII(M18)	28	26.49	396.90
		2VT/VT/12	PII(M12)	27	30.14	365.90
			PIII(M12+D7)	25	62.81	426.34
			PIII(M12+D21)	31	51.01	320.71
			PIII(M18)	29	17.79	189.35
CD8 CD40L	A/Indonesia	VT/IN/12	PI(M12)	32	2.09	28.38
			PII(M12+D7)	34	8.21	51.25
			PII(M12+D21)	34	5.43	73.31
			PII(M18)	34	3.52	49.19
		VT/VT/12	PI(M12)	30	3.66	26.90
			PII(M12+D7)	31	7.68	119.95
			PII(M12+D21)	37	5.98	61.91
			PII(M18)	36	4.22	56.87
		2VT/IN/12	PII(M12)	17	4.44	40.48
			PIII(M12+D7)	22	13.23	99.16
			PIII(M12+D21)	27	8.29	57.18
			PIII(M18)	24	2.45	37.14
		2VT/VT/12	PII(M12)	30	4.48	83.08
			PIII(M12+D7)	26	7.76	99.48
			PIII(M12+D21)	31	7.45	96.27
			PIII(M18)	28	2.75	36.15
	Split H5N1 A/Vietnam	VT/IN/12	PI(M12)	28	2.33	34.71
			PII(M12+D7)	31	4.40	30.87
			PII(M12+D21)	38	3.96	67.70
			PII(M18)	41	4.32	59.02
		VT/VT/12	PI(M12)	28	2.47	32.62
			PII(M12+D7)	33	2.90	183.17
			PII(M12+D21)	39	2.44	92.98
			PII(M18)	39	3.84	75.59
		2VT/IN/12	PII(M12)	17	2.16	52.15
			PIII(M12+D7)	23	2.90	39.63
			PIII(M12+D21)	28	3.11	32.25
			PIII(M18)	28	4.78	62.03
		2VT/VT/12	PII(M12)	27	2.87	40.66
			PIII(M12+D7)	25	10.59	52.19
			PIII(M12+D21)	31	3.70	34.54
			PIII(M18)	29	2.09	59.01
CD8 IL-2	A/Indonesia	VT/IN/12	PI(M12)	32	29.84	250.29
			PII(M12+D7)	34	55.96	393.80
			PII(M12+D21)	34	62.99	387.92
			PII(M18)	34	45.30	266.64
		VT/VT/12	PI(M12)	30	18.29	246.48

			PII(M12+D7)	31	36.88	268.94
			PII(M12+D21)	37	19.97	198.10
			PII(M18)	36	31.29	340.10
		2VT/IN/12	PII(M12)	17	17.80	236.04
			PIII(M12+D7)	22	28.07	261.31
			PIII(M12+D21)	27	31.51	216.34
			PIII(M18)	24	19.06	157.42
		2VT/VT/12	PII(M12)	30	28.56	430.21
			PIII(M12+D7)	26	61.72	318.59
			PIII(M12+D21)	31	43.10	277.22
			PIII(M18)	28	31.56	385.23
	A/Vietnam	VT/IN/12	PI(M12)	28	9.12	276.25
			PII(M12+D7)	31	20.48	385.51
			PII(M12+D21)	38	12.52	278.19
			PII(M18)	41	15.35	281.28
		VT/VT/12	PI(M12)	28	12.06	148.06
			PII(M12+D7)	33	23.40	399.09
			PII(M12+D21)	39	8.59	207.18
			PII(M18)	39	15.08	211.25
		2VT/IN/12	PII(M12)	17	8.22	80.21
			PIII(M12+D7)	23	8.29	278.07
			PIII(M12+D21)	28	14.20	208.85
			PIII(M18)	28	14.48	250.77
		2VT/VT/12	PII(M12)	27	35.92	362.09
			PIII(M12+D7)	25	52.32	392.40
			PIII(M12+D21)	31	47.66	280.88
			PIII(M18)	29	21.78	153.80
CD8 INF-γ	A/Indonesia	VT/IN/12	PI(M12)	32	10.22	195.65
			PII(M12+D7)	34	13.38	163.26
			PII(M12+D21)	34	13.88	121.34
			PII(M18)	34	8.53	121.12
		VT/VT/12	PI(M12)	30	6.58	85.93
			PII(M12+D7)	31	15.65	111.26
			PII(M12+D21)	37	7.48	123.95
			PII(M18)	36	12.19	79.29
		2VT/IN/12	PII(M12)	17	19.40	172.59
			PIII(M12+D7)	22	10.25	163.04
			PIII(M12+D21)	27	6.66	65.20
			PIII(M18)	24	7.77	113.83
		2VT/VT/12	PII(M12)	30	13.70	342.47
			PIII(M12+D7)	26	18.89	170.88
			PIII(M12+D21)	31	13.34	135.85
			PIII(M18)	28	6.53	164.84
	A/Vietnam	VT/IN/12	PI(M12)	28	5.79	214.35
			PII(M12+D7)	31	7.58	253.61
			PII(M12+D21)	38	11.90	273.59
			PII(M18)	41	13.33	342.90
		VT/VT/12	PI(M12)	28	7.07	174.18
			PII(M12+D7)	33	7.45	181.01
			PII(M12+D21)	39	6.84	235.75
			PII(M18)	39	9.36	182.90
		2VT/IN/12	PII(M12)	17	4.31	101.18
			PIII(M12+D7)	23	7.59	236.89
			PIII(M12+D21)	28	6.18	111.67
			PIII(M18)	28	5.10	351.48
		2VT/VT/12	PII(M12)	27	9.04	120.34

			PIII(M12+D7)	25	41.24	348.65
			PIII(M12+D21)	31	15.18	269.18
			PIII(M18)	29	7.33	135.83
CD8 TNF-α	A/Indonesia	VT/IN/12	PI(M12)	32	29.30	263.60
			PII(M12+D7)	34	54.30	362.16
			PII(M12+D21)	34	48.83	375.84
			PII(M18)	34	41.13	261.84
		VT/VT/12	PI(M12)	30	15.38	263.83
			PII(M12+D7)	31	34.22	261.37
			PII(M12+D21)	37	23.41	155.91
			PII(M18)	36	24.97	337.40
		2VT/IN/12	PII(M12)	17	24.41	194.37
			PIII(M12+D7)	22	35.18	233.51
			PIII(M12+D21)	27	31.57	210.43
			PIII(M18)	24	27.31	164.07
		2VT/VT/12	PII(M12)	30	25.59	330.65
			PIII(M12+D7)	26	32.53	309.18
			PIII(M12+D21)	31	45.94	281.82
			PIII(M18)	28	31.10	361.58
	A/Vietnam	VT/IN/12	PI(M12)	28	8.92	240.77
			PII(M12+D7)	31	10.89	363.87
			PII(M12+D21)	38	14.75	282.33
			PII(M18)	41	16.41	310.32
		VT/VT/12	PI(M12)	28	11.32	106.95
			PII(M12+D7)	33	17.27	340.50
			PII(M12+D21)	39	10.85	228.98
			PII(M18)	39	14.16	217.05
		2VT/IN/12	PII(M12)	17	6.46	81.15
			PIII(M12+D7)	23	8.21	300.02
			PIII(M12+D21)	28	8.45	210.82
			PIII(M18)	28	16.70	368.21
		2VT/VT/12	PII(M12)	27	19.46	337.02
			PIII(M12+D7)	25	44.13	394.01
			PIII(M12+D21)	31	35.54	288.39
			PIII(M18)	29	18.60	170.85

N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
CD8-CD40L: CD8 T-cells producing at least CD40L and another cytokine
CD8-IL-2: CD8 T-cells producing at least IL2 and another cytokine
CD8-INFγ: CD8 T-cells producing at least INF gamma and another cytokine
CD8-TNFα: CD8 T-cells producing at least TNF alpha and another cytokine

Safety Results: Number (%) of subjects with unsolicited AEs reported at Month 6 + 30 Days (Day 0-29) (Total vaccinated cohort)

Most frequent adverse events - On-Therapy (occurring within day 0-29 following vaccination)	**VT/VT/6 Group N = 66**	**VT/IN/6 Group N = 63**	**VT/VT/12 Group N = 64**	**VT/IN/12 Group N = 64**	**2VT/VT/6 Group N = 63**	**2VT/IN/6 Group N = 64**	**2VT/VT/12 Group N = 63**	**2VT/IN/12 Group N = 65**
Subjects with any AE(s), n (%)	19 (28.8)	31 (49.2)	10 (15.6)	18 (28.1)	28 (44.4)	32 (50.0)	24 (38.1)	19 (29.2)
Subjects with grade 3 AE(s), n(%)	4 (6.1)	3 (4.8)	2 (3.1)	0 (0.0)	3 (4.8)	2 (3.1)	7 (11.1)	1 (1.5)
Subjects with related AE(s), n(%)	11 (16.7)	12 (19.0)	3 (4.7)	5 (7.8)	15 (23.8)	11 (17.2)	6 (9.5)	6 (9.2)
Nasopharyngitis	5 (7.6)	8 (12.7)	2 (3.1)	4 (6.3)	11 (17.5)	7 (10.9)	3 (4.8)	6 (9.2)
Headache	4 (6.1)	3 (4.8)	-	4 (6.3)	4 (6.3)	4 (6.3)	2 (3.2)	4 (6.2)

Lymphadenopathy	3 (4.5)	-	-	1 (1.6)	3 (4.8)	2 (3.1)	2 (3.2)	-
Nausea	-	2 (3.2)	-	1 (1.6)	3 (4.8)	3 (4.7)	2 (3.2)	-
Diarrhoea	-	2 (3.2)	1 (1.6)	1 (1.6)	-	-	4 (6.3)	2 (3.1)
Back pain	-	-	-	1 (1.6)	2 (3.2)	2 (3.1)	-	-
Cough	-	-	-	1 (1.6)	2 (3.2)	-	-	1 (1.5)
Injection site pruritus	2 (3.0)	-	1 (1.6)	-	-	-	-	1 (1.5)
Pharyngolaryngeal pain	-	-	-	2 (3.1)	-	2 (3.1)	-	-
Bronchitis	2 (3.0)	-	-	-	-	-	-	1 (1.5)
Hyperaesthesia	-	-	-	1 (1.6)	-	-	2 (3.2)	-
Influenza like illness	-	-	-	-	-	2 (3.1)	-	1 (1.5)
Upper respiratory tract infection	-	-	-	1 (1.6)	2 (3.2)	-	-	-
Vomiting	-	-	-	-	-	-	2 (3.2)	1 (1.5)
Abdominal pain	2 (3.0)	-	-	-	-	-	-	-
Abdominal pain upper	-	-	-	-	2 (3.2)	-	-	-
Arthralgia	2 (3.0)	-	-	-	-	-	-	-
Chills	-	-	2 (3.1)	-	-	-	-	-
Injection site lymphadenopathy	-	-	-	-	-	2 (3.1)	-	-
Injection site warmth	-	2 (3.2)	-	-	-	-	-	-
Myalgia	-	-	-	-	2 (3.2)	-	-	-
Pharyngitis	-	-	-	1 (1.6)	-	-	-	1 (1.5)
Rhinitis	-	-	-	1 (1.6)	-	-	-	1 (1.5)
Sinusitis	-	-	-	-	-	-	2 (3.2)	-
Thirst	-	-	-	2 (3.1)	-	-	-	-
Tonsillitis	-	-	-	-	2 (3.2)	-	-	-
Vertigo	-	-	1 (1.6)	-	-	-	-	1 (1.5)
Aggression	-	-	-	1 (1.6)	-	-	-	-
Allergy to metals	-	-	1 (1.6)	-	-	-	-	-
Asthenia	-	-	1 (1.6)	-	-	-	-	-
Colonoscopy	-	-	-	-	-	-	-	1 (1.5)
Dermatitis acneiform	-	-	1 (1.6)	-	-	-	-	-
Dermatitis contact	-	-	1 (1.6)	-	-	-	-	-
Dizziness	-	-	-	1 (1.6)	-	-	-	-
Dysmenorrhoea	-	-	-	-	-	-	-	1 (1.5)
Gastritis	-	-	-	-	-	-	-	1 (1.5)
Gastroenteritis	-	-	1 (1.6)	-	-	-	-	-
Gastrointestinal disorder	-	-	-	1 (1.6)	-	-	-	-
Gingivitis	-	-	1 (1.6)	-	-	-	-	-
Hunger	-	-	-	1 (1.6)	-	-	-	-
Hyperhidrosis	-	-	-	-	-	-	-	1 (1.5)
Incontinence	-	-	-	-	-	-	-	1 (1.5)
Injection site paraesthesia	-	-	-	1 (1.6)	-	-	-	-
Peripheral coldness	-	-	-	1 (1.6)	-	-	-	-
Pneumonia	-	-	1 (1.6)	-	-	-	-	-
Pyrexia	-	-	-	-	-	-	-	1 (1.5)
Respiratory disorder	-	-	-	1 (1.6)	-	-	-	-
Tooth extraction	-	-	-	1 (1.6)	-	-	-	-
Toothache	-	-	-	-	-	-	-	1 (1.5)
Wound infection	-	-	-	1 (1.6)	-	-	-	-
- : Adverse event absent or not meeting the selected AE counting rule: > 30 subjects/treatment group and > 3 groups, display the most frequent 5 events in each treatment group								
Safety Results: Number (%) of subjects with unsolicited AEs reported at Month 12+ 30 Days (Day 0-29) (Total vaccinated cohort)								
Most frequent adverse events - On-Therapy (occurring	**VT/VT/6 Group -**	**VT/IN/6 Group -**	**VT/VT/12 Group N = 58**	**VT/IN/12 Group N = 62**	**2VT/VT/6 Group -**	**2VT/IN/6 Group -**	**2VT/VT/12 Group N = 53**	**2VT/IN/12 Group N = 56**

within day 0-29 following vaccination)								
Subjects with any AE(s), n (%)	-	-	10 (17.2)	16 (25.8)	-	-	14 (26.4)	16 (28.6)
Subjects with grade 3 AE(s), n(%)	-	-	2 (3.4)	2 (3.2)	-	-	1 (1.9)	2 (3.6)
Subjects with related AE(s), n(%)	-	-	4 (6.9)	7 (11.3)	-	-	9 (17.0)	9 (16.1)
Lymphadenopathy	-	-	-	3 (4.8)	-	-	2 (3.8)	4 (7.1)
Ear pain	-	-	-	1 (1.6)	-	-	1 (1.9)	-
Vertigo	-	-	1 (1.7)	1 (1.6)	-	-	-	-
Diarrhoea	-	-	1 (1.7)	-	-	-	-	-
Dyspepsia	-	-	-	1 (1.6)	-	-	-	-
Nausea	-	-	1 (1.7)	-	-	-	1 (1.9)	2 (3.6)
Toothache	-	-	-	-	-	-	1 (1.9)	-
Asthenia	-	-	1 (1.7)	-	-	-	-	-
Axillary pain	-	-	-	-	-	-	1 (1.9)	-
Influenza like illness	-	-	1 (1.7)	-	-	-	-	-
Injection site erythema	-	-	1 (1.7)	-	-	-	-	-
Injection site irritation	-	-	-	1 (1.6)	-	-	-	-
Injection site pruritus	-	-	1 (1.7)	-	-	-	2 (3.8)	3 (5.4)
Pyrexia	-	-	2 (3.4)	1 (1.6)	-	-	-	-
Seasonal allergy	-	-	1 (1.7)	-	-	-	-	-
Gastroenteritis	-	-	1 (1.7)	-	-	-	-	-
Nasopharyngitis	-	-	4 (6.9)	3 (4.8)	-	-	-	3 (5.4)
Oral herpes	-	-	-	1 (1.6)	-	-	-	2 (3.6)
Rhinitis	-	-	1 (1.7)	1 (1.6)	-	-	2 (3.8)	-
Sinusitis	-	-	-	1 (1.6)	-	-	1 (1.9)	-
Varicella	-	-	-	1 (1.6)	-	-	-	-
Vulvovaginal mycotic infection	-	-	-	-	-	-	1 (1.9)	-
Arthralgia	-	-	-	1 (1.6)	-	-	-	-
Musculoskeletal chest pain	-	-	-	1 (1.6)	-	-	-	-
Myalgia	-	-	1 (1.7)	-	-	-	-	-
Leiomyoma	-	-	-	1 (1.6)	-	-	-	-
Dizziness	-	-	-	-	-	-	1 (1.9)	-
Headache	-	-	-	-	-	-	2 (3.8)	-
Hemicephalalgia	-	-	-	1 (1.6)	-	-	-	-
Poor quality sleep	-	-	1 (1.7)	-	-	-	-	-
Insomnia	-	-	-	-	-	-	1 (1.9)	-
Menstrual disorder	-	-	-	1 (1.6)	-	-	-	-
Uterine enlargement	-	-	-	1 (1.6)	-	-	-	-
Cough	-	-	1 (1.7)	1 (1.6)	-	-	-	-
Oropharyngeal pain	-	-	1 (1.7)	1 (1.6)	-	-	1 (1.9)	-
Pruritus	-	-	1 (1.7)	-	-	-	-	-
Shock	-	-	-	1 (1.6)	-	-	-	-

- : Adverse event absent or not meeting the selected AE counting rule: > 30 subjects/treatment group and > 3 groups, display the most frequent 5 events in each treatment group

Safety Results: Number (%) of subjects with unsolicited AEs for the entire study period (Total vaccinated cohort)

Most frequent adverse events	**VT/VT/6 Group N = 66**	**VT/IN/6 Group N = 63**	**VT/VT/12 Group N = 64**	**VT/IN/12 Group N = 64**	**2VT/VT/6 Group N = 63**	**2VT/IN/6 Group N = 64**	**2VT/VT/12 Group N = 63**	**2VT/IN/12 Group N = 65**
Subjects with any AE(s), n (%)	23 (34.8)	35 (55.6)	24 (37.5)	27 (42.2)	31 (49.2)	32 (50.0)	31 (49.2)	30 (46.2)
Nasopharyngitis	5 (7.6)	8 (12.7)	8 (12.5)	8 (12.5)	11 (17.5)	7 (10.9)	5 (7.9)	10 (15.4)
Headache	5 (7.6)	3 (4.8)	-	4 (6.3)	4 (6.3)	4 (6.3)	3 (4.8)	4 (6.2)
Lymphadenopathy	3 (4.5)	-	-	3 (4.7)	3 (4.8)	2 (3.1)	3 (4.8)	4 (6.2)
Nausea	-	2 (3.2)	-	-	3 (4.8)	3 (4.7)	3 (4.8)	2 (3.1)
Diarrhoea	-	2 (3.2)	2 (3.1)	-	-	-	4 (6.3)	2 (3.1)

Injection site pruritus	2 (3.0)	-	2 (3.1)	-	-	-	-	3 (4.6)
Influenza like illness	-	-	-	-	-	3 (4.7)	-	2 (3.1)
Oropharyngeal pain	-	-	-	3 (4.7)	-	2 (3.1)	-	-
Rhinitis	-	-	-	2 (3.1)	-	-	3 (4.8)	-
Cough	-	-	-	2 (3.1)	-	-	-	2 (3.1)
Pyrexia	-	-	3 (4.7)	-	-	-	-	-
Tonsillitis	-	-	-	-	3 (4.8)	-	-	-
Abdominal pain	2 (3.0)	-	-	-	-	-	-	-
Arthralgia	2 (3.0)	-	-	-	-	-	-	-
Asthenia	-	-	2 (3.1)	-	-	-	-	-
Back pain	-	-	-	-	-	2 (3.1)	-	-
Bronchitis	2 (3.0)	-	-	-	-	-	-	-
Chills	-	-	2 (3.1)	-	-	-	-	-
Gastritis	-	-	-	-	-	-	-	2 (3.1)
Gastroenteritis	-	-	2 (3.1)	-	-	-	-	-
Injection site lymphadenopathy	-	-	-	-	-	2 (3.1)	-	-
Injection site warmth	-	2 (3.2)	-	-	-	-	-	-
Oral herpes	-	-	-	-	-	-	-	2 (3.1)
Thirst	-	-	-	2 (3.1)	-	-	-	-
Vomiting	-	-	-	-	-	-	-	2 (3.1)

- : Adverse event absent or not meeting the selected AE counting rule: > 30 subjects/treatment group and > 3 groups, display the most frequent 5 events in each treatment group

Safety Results: Number (%) of subjects with SAEs reported up to Month 6 + 30 days (Total vaccinated cohort), n (%) [n assessed by the investigator as related to study medication]

All SAEs	**VT/VT/6 Group N = 66**	**VT/IN/6 Group N = 63**	**VT/VT/12 Group N = 64**	**VT/IN/12 Group N = 64**	**2VT/VT/6 Group N = 63**	**2VT/IN/6 Group N = 64**	**2VT/VT/12 Group N = 63**	**2VT/IN/12 Group N = 65**
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	0(0.0)[0]	1(1.6)[0]	3(4.7)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	1(1.5)[0]
Cerebral infarction	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Cervicobrachial syndrome	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Concussion	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Hemiparesis	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Traumatic brain injury	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Uterine neoplasm	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.5)[0]
Uterine polyp	0(0.0)[0]	0 0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]
Fatal SAEs	**VT/VT/6 Group N = 66**	**VT/IN/6 Group N = 63**	**VT/VT/12 Group N = 64**	**VT/IN/12 Group N = 64**	**2VT/VT/6 Group N = 63**	**2VT/IN/6 Group N = 64**	**2VT/VT/12 Group N = 63**	**2VT/IN/12 Group N = 65**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Traumatic brain injury	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]

Safety Results: Number (%) of subjects with SAEs reported during Month 6 + Day 30 to Month 12 + Day 30 (Total vaccinated cohort), n (%) [n assessed by the investigator as related to study medication]

All SAEs	**VT/VT/6 Group N = 66**	**VT/IN/6 Group N = 63**	**VT/VT/12 Group N = 64**	**VT/IN/12 Group N = 64**	**2VT/VT/6 Group N = 63**	**2VT/IN/6 Group N = 64**	**2VT/VT/12 Group N = 63**	**2VT/IN/12 Group N = 65**
Subjects with any SAE(s), n (%)[n assessed by investigator as related]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	2(3.2)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]
Ankle fracture	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Tonsillitis	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Leiomyoma	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Uterine leiomyoma	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]

Fatal SAEs	VT/VT/6 N = 66	VT/IN/6 N = 63	VT/VT/12 N = 64	VT/IN/12 N = 64	2VT/VT/6 N = 63	2VT/IN/6 N = 64	2VT/VT/12 N = 63	2VT/IN/12 N = 65
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]

Safety Results: Number (%) of subjects with SAEs reported during Month 12 + Day 30 to Month 18 (Total vaccinated cohort), n (%) [n assessed by the investigator as related to study medication]

All SAEs	VT/VT/6 Group N = 66	VT/IN/6 Group N = 63	VT/VT/12 Group N = 64	VT/IN/12 Group N = 64	2VT/VT/6 Group N = 63	2VT/IN/6 Group N = 64	2VT/VT/12 Group N = 63	2VT/IN/12 Group N = 65
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	1(1.5)[0]	3(4.8)[0]	2(3.1)[1]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]
Skin laceration	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Cellulitis	1(1.5)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Hypoaesthesia	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Intervertebral disc protrusion	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Multiple sclerosis	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Myocardial infarction	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]
Non-hodgkin's lymphoma	0(0.0)[0]	0(0.0)[0]	1(1.6)[1]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Sick sinus syndrome	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Soft tissue injury	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Fatal SAEs	**VT/VT/6 Group N = 66**	**VT/IN/6 Group N = 63**	**VT/VT/12 Group N = 64**	**VT/IN/12 Group N = 64**	**2VT/VT/6 Group N = 63**	**2VT/IN/6 Group N = 64**	**2VT/VT/12 Group N = 63**	**2VT/IN/12 Group N = 65**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]

Safety Results: Number (%) of subjects with SAEs for the entire study period (Total vaccinated cohort), n (%) [n assessed by the investigator as related to study medication]

All SAEs	VT/VT/6 Group N = 66	VT/IN/6 Group N = 63	VT/VT/12 Group N = 64	VT/IN/12 Group N = 64	2VT/VT/6 Group N = 63	2VT/IN/6 Group N = 64	2VT/VT/12 Group N = 63	2VT/IN/12 Group N = 65
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	1(1.5)[0]	4(6.3)[0]	5(7.8)[1]	1(1.6)[0]	3(4.8)[0]	0(0.0)[0]	3(4.8)[0]	1(1.5)[0]
Skin laceration	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Ankle fracture	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Cellulitis	1(1.5)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Cerebral infarction	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Cervicobrachial syndrome	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Concussion	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Hemiparesis	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Hypoaesthesia	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Intervertebral disc protrusion	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Leiomyoma	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Multiple sclerosis	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Myocardial infarction	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]
Non-hodgkin's lymphoma	0(0.0)[0]	0(0.0)[0]	1(1.6)[1]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Sick sinus syndrome	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Soft tissue injury	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Tonsillitis	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Traumatic brain injury	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Uterine leiomyoma	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]
Uterine neoplasm	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.5)[0]
Uterine polyp	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]

Fatal SAEs	VT/VT/6 Group N = 66	VT/IN/6 Group N = 63	VT/VT/12 Group N = 64	VT/IN/12 Group N = 64	2VT/VT/6 Group N = 63	2VT/IN/6 Group N = 64	2VT/VT/12 Group N = 63	2VT/IN/12 Group N = 65
subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0(0.0)[0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Traumatic brain injury	0(0.0 [0]	0(0.0)[0]	1(1.6)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]

Conclusion: Please refer to the publications section.

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