ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 01/15/2013

Grantor: CBER IND/IDE Number: 11580 Serial Number:

Efficacy Study of Two Influenza Vaccines and Placebo in Healthy Adult Subjects

This study has been completed.

Sponsor:	Novartis Vaccines
Collaborators:	Novartis Vaccines
Information provided by (Responsible Party):	Novartis (Novartis Vaccines)
ClinicalTrials.gov Identifier:	NCT00630331

Purpose

The present study will evaluate clinical efficacy, safety, tolerability and immunogenicity of both Novartis Vaccines' cell-derived influenza vaccine and egg-derived influenza vaccine in healthy adults 18 to 49 years of age.

Condition	Intervention	Phase
Influenza	Biological/Vaccine: Cell culture-derived influenza vaccine Biological/Vaccine: Egg-derived influenza virus vaccine Biological/Vaccine: Placebo	Phase 3

Study Type: Interventional
Study Design: Prevention, Parallel Assignment, Single Blind (Subject), Randomized, Safety/Efficacy Study
Official Title: A Phase III, Randomized, Observer-Blind, Placebo-Controlled, Multicenter Study to Assess Clinical Efficacy of a Cell-Derived Subunit Influenza Vaccine and an Egg-Derived Subunit Influenza Vaccine in the 2007-2008 Influenza Season in Healthy Adult Subjects

Further study details as provided by Novartis (Novartis Vaccines):
Primary Outcome Measure:

- Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains [Time Frame: 6 Months] [Designated as safety issue: No]
  The vaccine efficacy of CCI and IVV vaccines was estimated relative to Placebo group as the number of subjects prevented against virus-confirmed symptomatic influenza illness caused by each of three vaccine-like virus strains.

Secondary Outcome Measures:

- Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains [Time Frame: 6 Months] [Designated as safety issue: No]
  The vaccine efficacy of CCI and IVV vaccines was estimated relative to placebo group as the number of subjects prevented against virus-confirmed symptomatic influenza A or B illness caused by non-vaccine-like strains.
- Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains [Time Frame: 6 Months] [Designated as safety issue: No]
  The vaccine efficacy of CCI and IVV vaccines was estimated relative to placebo as the number of subjected prevented against virus-confirmed symptomatic influenza A or B illness caused by vaccine-like and non-vaccine-like strains.
- Influenza-Associated Days in Bed, All Subjects [Time Frame: 6 Months] [Designated as safety issue: No]
  The number of subjects in this analysis included all subjects in the per protocol efficacy population.
- Influenza-Associated Days in Bed, Subset of Subjects With Virus-Confirmed- Influenza [Time Frame: 6 Months] [Designated as safety issue: No]
  The analysis was done among the subset of subjects in the per protocol efficacy population who had culture-confirmed influenza.
- Number Of Medical Visits (Inpatient and Outpatient) Due to Influenza Illness or Symptoms of Influenza, All Subjects [Time Frame: 6 Months] [Designated as safety issue: No]
  The number of subjects in this analysis included all subjects in the per protocol efficacy population.
- Number of Medical Visits (Inpatient and Outpatient), Subset of Subjects With Virus-Confirmed-Influenza [Time Frame: 6 Months] [Designated as safety issue: No]
  The analysis was done among the subset of subjects in the per protocol efficacy population who had culture-confirmed influenza.
- Number of Days of Usual Activity (i.e. Job, School,Household/Family/Community Activities) Lost Due to Influenza Disease, All Subjects [Time Frame: 6 Months] [Designated as safety issue: No]
  The number of subjects in this analysis included all subjects in the per protocol efficacy population.
- Number of Days of Usual Activity (i.e. Job, School,Household/Family/Community Activities) Lost, Subset of Subjects With Virus-Confirmed-Influenza [Time Frame: 6 Months] [Designated as safety issue: No]
  The analysis was done among the subset of subjects in the per protocol efficacy population who had culture-confirmed influenza.
- Percentages of Subjects Who Achieved HI Titers ≥40 After One Vaccination of Either Cell-culture Derived or Egg-derived Influenza Vaccine or Placebo [Time Frame: Before vaccination (day 1) and three weeks after vaccination (day 22)] [Designated as safety issue: No]
  Immunogenicity was measured as the percentage of subjects achieving HI titers ≥40 at baseline (day 1) and three weeks after (day 22) one vaccination of either cell-culture or egg-derived vaccine or placebo for each of the three influenza vaccine strains (A/H1N1, A/H3N2 and B), evaluated using hemagglutination inhibition (HI) egg-derived antigen assay. This criterion is met according to US (CBER) guideline if the lower limit of the two-sided 95% CI for the percentage of subjects achieving HI titers ≥40 is ≥70%.
- Percentages of Subjects Achieving Seroconversion After One Vaccination of Either Cell-culture Derived or Egg-derived Influenza Vaccine or Placebo [Time Frame: Three weeks after vaccination (day 22)] [Designated as safety issue: No]
  As per the CBER guideline, seroconversion is defined as the percentage of subjects with a prevaccination HI titer <10, a postvaccination titer ≥40; or in subjects with prevaccination HI titer ≥10, a ≥4-fold increase in postvaccination HI antibody titer. According to CBER criteria, the lower limit of the two-sided 95% CI for the percentage of subjects achieving seroconversion for HI antibody titer at day 22 met exceeded 40%.
- Number of Subjects Reported Solicited Local and Systemic Reactions up to 7 Days After Vaccination [Time Frame: Up to 7 days post vaccination] [Designated as safety issue: Yes]
  The solicited local and systemic reactogenicity were collected up to 7 days after vaccination for all three vaccine groups.

Enrollment: 11404
Study Start Date: October 2007

Primary Completion Date: July 2008
Study Completion Date: July 2008

Arms	Assigned Interventions
Experimental: CCI Subjects received one dose of cell culture-derived influenza vaccine.	Biological/Vaccine: Cell culture-derived influenza vaccine One dose (0.5 mL) of cell culture-derived influenza vaccine, administered in the deltoid muscle.
Experimental: IVV Subjects received one dose of the trivalent egg-derived influenza vaccine.	Biological/Vaccine: Egg-derived influenza virus vaccine One dose (0.5 mL) of the trivalent egg-derived influenza virus vaccine, administered in the deltoid muscle.
Placebo Comparator: Placebo Subjects received one dose of phosphate buffered solution (PBS).	Biological/Vaccine: Placebo One dose (0.5 mL) of phosphate buffered solution.

Eligibility

Ages Eligible for Study: 18 Years to 49 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

1. subjects 18 to 49 years of age;
2. in good health as determined by medical history and physical examination;
3. able and willing to provide written informed consent prior to any study procedure;
4. able to comply with all study procedures, including availability and willingness to be actively followed throughout the ensuing influenza season with weekly telephone calls and to comply with the need for prompt collection of nasal and throat specimens in the event of influenza symptoms.

Exclusion Criteria:

1. history of anaphylaxis or serious reaction after administration of any vaccine, or hypersensitivity to eggs, egg protein, chicken feathers, influenza viral protein, neomycin, kanamycin, or any other vaccine component, chemically related substance, or component of the potential packaging materials;
2. any health condition for which the inactivated vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) including chronic diseases of the pulmonary or cardiovascular systems (including asthma), chronic metabolic diseases (including diabetes), renal dysfunction, hemoglobinopathies, immune deficiency disease (including HIV infection) or on-going immunosuppressive therapy;
3. employment in professions prone to influenza transmission to or from high-risk populations (this exclusion specifically includes nurses, physicians, all other healthcare workers with direct patient contact; and police, fire, and rescue personnel); or living in the same household as an immunocompromised person;
4. history of Guillain-Barré syndrome;
5. bleeding diathesis;

6. receipt of another investigational agent within 90 days prior to enrollment in the study or before completion of the safety follow-up period in another study, whichever is longer, and unwilling to refuse participation in another clinical study through the end of the study;
7. receipt of another vaccine within 2 weeks (for inactivated vaccines) or 4 weeks (for live vaccines) prior to Visit 1;
8. laboratory-confirmed influenza disease within 6 months prior to Visit 1;
9. receipt of an influenza vaccine within 6 months prior to Visit 1 or plans to receive influenza vaccine outside of this study;
10. experienced a temperature (≥100.0°F / ≥37.8°C) and/or any acute illness within 3 days prior to study vaccination;
11. pregnant or breast-feeding female;
12. if female of childbearing potential and sexually active, has not used any of the birth control methods detailed in the section entitled “Females of Childbearing Potential” for at least 2 months prior to study entry;
13. if female of childbearing potential and sexually active, refusal to use a reliable contraceptive method as detailed in the section entitled “Females of Childbearing Potential” during the first 3 weeks after vaccination;
14. research staff directly involved with the clinical study or family members or household members of research staff. Research staff are individuals with direct or indirect contact with study subjects, or study site personnel who have access to any study documents containing subject information. This would include receptionists, persons scheduling appointments or making screening calls, regulatory specialists, laboratory technicians, etc.;
15. any condition which, in the opinion of the investigator, might interfere with the evaluation of the study objectives or with the safety of the study subject.

Contacts and Locations

Locations

United States, Colorado
- Site 14
  - Denver, Colorado, United States, 80212

United States, Florida
- Site 15
  - Pembroke Pines, Florida, United States, 33024
- Site 17
  - South Miami, Florida, United States, 33143

United States, Kansas
- Site 13
  - Lenexa, Kansas, United States, 66219

United States, Kentucky
- Site 2
  - Bardstown, Kentucky, United States, 40004

United States, Missouri
- Site 1
  - St. Louis, Missouri, United States, 63140

United States, New Jersey
- Site 4
  - Edison, New Jersey, United States, 08817

United States, New York
- Site 10
  - Binghamton, New York, United States, 13901
- Site 5
  - Endwell, New York, United States, 13760

United States, North Carolina
Site 16
Winston-Salem, North Carolina, United States, 27103
United States, Rhode Island
Site 11
Warwick, Rhode Island, United States, 02886
United States, South Carolina
Site 12
Anderson, South Carolina, United States, 29621
United States, Texas
Site 9
Austin, Texas, United States, 78705
Site 8
Dallas, Texas, United States, 75234
United States, Utah
Site 3
Salt Lake City, Utah, United States, 84121
Site 7
Salt Lake City, Utah, United States, 84109
United States, Virginia
Site 6
Burke, Virginia, United States, 22105
Finland
Site 25
Espoo, Finland, 02100
Site 26
Helsinki, Finland, 00100
Site 27
Helsinki, Finland, 00930
Site 33
Järvenpää, Finland, 04400
Site 35
Kokkola, Finland, 67100
Site 34
Kotka, Finland, 48600
Site 30
Kuopio, Finland, 70100
Site 22
Lahti, Finland, 15140
Site 31
Oulu, Finland, 90100
Site 23
Pori, Finland, 28120
Site 32
Seinäjoki, Finland, 60100

Site 21
Tampere, Finland, 33100
Site 24
Turku, Finland, 20520
Site 28
Vantaa, Finland, 01300
Site 29
Vantaa, Finland, 01600
Poland
Site 49
Bydgoszcz, Poland, 85-316
Site 53
Gniewkowo, Poland, 88-140
Site 59
Katowice, Poland, 40-084
Site 63
Kielce, Poland, 25-711
Site 62
Końskie, Poland, 26-200
Site 57
Krakow, Poland, 30-510
Site 41
Kraków, Poland, 30-969
Site 42
Kraków, Poland, 31-503
Site 43
Kraków, Poland, 31-115
Site 50
Kraków, Poland, 31-832
Site 44
Lubartów, Poland, 21 - 100
Site 45
Lublin, Poland, 20-044
Site 65
Oleśnica, Poland, 56-400
Site 46
Olsztyn, Poland, 10-461
Site 47
Olsztyn, Poland, 10-117
Site 48
Olsztyn, Poland, 10-295
Site 58
Radziszów, Poland, 32-052
Site 61
Ruda Śląska, Poland, 41-703

Site 60
Rzeszów, Poland, 35-324
Site 52
Warszawa, Poland, 02-777
Site 55
Wilkowice, Poland, 43-365
Site 64
Wrocław, Poland, 51-312
Site 54
Wąbrzeźno, Poland, 87-200
Site 51
Łodź, Poland, 90-302

Investigators

Study Chair:	Novartis Vaccines	Novartis Vaccines

More Information

Results Publications:

Frey S, Vesikari T, Szymczakiewicz-Multanowska A, Lattanzi M, Izu A, Groth N, Holmes S. Clinical efficacy of cell culture-derived and egg-derived inactivated subunit influenza vaccines in healthy adults. Clin Infect Dis. 2010 Nov 1;51(9):997-1004. doi: 10.1086/656578.

Responsible Party:	Novartis Vaccines
Study ID Numbers:	V58P13 2007-002871-15 11580
Health Authority:	United States: Food and Drug Administration Finland: Finnish Medicines Agency Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Study Results

Participant Flow

Recruitment Details	Participants were enrolled at multiple centres in the US, Poland and Finland.
Pre-Assignment Details	All enrolled subjects were included in the trial.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Overall Study

	CCI Vaccine	IVV Vaccine	Placebo
Started	3828	3676	3900
Completed	3622	3510	3712
Not Completed	206	166	188
Death	2	1	1
Adverse Event	1	0	0
Withdrawal by Subject	12	7	5
Lost to Follow-up	175	143	170
Inappropriate enrollment	3	6	3
Unable to classify	9	4	3
Protocol Violation	4	5	6

Baseline Characteristics

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Baseline Measures

	CCI Vaccine	IVV Vaccine	Placebo	Total
Number of Participants	3828	3676	3900	11404
Age, Continuous [units: years]	32.7 (10.1)	33.0 (10.2)	32.7 (10.2)	32.8 (10.2)

	CCI Vaccine	IVV Vaccine	Placebo	Total
Mean (Standard Deviation)				
Gender, Customized [units: Subjects]				
Female	2088	2026	2176	6290
Male	1740	1649	1722	5111
Not Available	0	1	2	3

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains
Measure Description	The vaccine efficacy of CCI and IVV vaccines was estimated relative to Placebo group as the number of subjects prevented against virus-confirmed symptomatic influenza illness caused by each of three vaccine-like virus strains.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was performed on per protocol (PP) efficacy population i.e. the subjects in the exposed efficacy population who correctly received the vaccine and provided evaluable swab samples at the relevant time points.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	3776	3638	3843
Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains [units: Subjects]			
Overall	7	9	44

	CCI Vaccine	IVV Vaccine	Placebo
A/Wisconsin/67/2005 (H3N2)-like	2	1	0
A/Solomon Islands/3/2006 (H1N1)-like	5	8	43
B/Malaysia/2506/2004-like	0	0	1

Statistical Analysis 1 for Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo (Overall) Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	83.8
	Confidence Interval	(1-Sided) 97.5% 61.0
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for A/H1N1 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	88.2
	Confidence Interval	(1-Sided) 97.5% 67.4
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for A/H3N2 strain. Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.999
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	For strain A/H3N2, the vaccine efficacy of the CCI vaccine vs. placebo was not evaluable since no influenza case was observed in the placebo group.

Statistical Analysis 4 for Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for B strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.394
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	100
	Confidence Interval	(1-Sided) 97.5% - 410
	Estimation Comments	[Not specified]

Statistical Analysis 5 for Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo (Overall) Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.004
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.

	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	78.4
	Confidence Interval	(1-Sided) 97.5% 52.1
	Estimation Comments	[Not specified]

Statistical Analysis 6 for Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for A/H1N1 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.002
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	80.3
	Confidence Interval	(1-Sided) 97.5% 54.7
	Estimation Comments	[Not specified]

Statistical Analysis 7 for Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo

	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for A/H3N2 strain. Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.992
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	For strain A/H3N2, the vaccine efficacy of the IVV vaccine vs. placebo was not evaluable since no influenza case was observed in the placebo group.

Statistical Analysis 8 for Number of Subjects With Culture-Confirmed Influenza Illness Caused by Vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for B strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.400
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	100
	Confidence Interval	(1-Sided) 97.5% - 429.4

	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains
Measure Description	The vaccine efficacy of CCI and IVV vaccines was estimated relative to placebo group as the number of subjects prevented against virus-confirmed symptomatic influenza A or B illness caused by non-vaccine-like strains.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was done on PP efficacy population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	3776	3638	3843
Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains [units: Subjects]			
Overall	30	29	74
A/H3N2	0	2	8
A/H1N1	1	0	8
B	29	27	59

Statistical Analysis 1 for Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo

	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo (Overall) Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.078
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	58.7
	Confidence Interval	(1-Sided) 97.5% 33.5
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for A/H1N1 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.104
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	87.3
	Confidence Interval	(1-Sided) 97.5% 4.6
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for A/H3N2 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.030
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	100
	Confidence Interval	(1-Sided) 97.5% 36.3
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo

	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for B strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.376
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	50.0
	Confidence Interval	(1-Sided) 97.5% 17.5
	Estimation Comments	[Not specified]

Statistical Analysis 5 for Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo (Overall) Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.085
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	58.6
	Confidence Interval	(1-Sided) 97.5% 32.9
	Estimation Comments	[Not specified]

Statistical Analysis 6 for Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for A/H1N1 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.033
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	100
	Confidence Interval	(1-Sided) 97.5% 33.9
	Estimation Comments	[Not specified]

Statistical Analysis 7 for Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo

	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for A/H3N2 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.265
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	73.6
	Confidence Interval	(1-Sided) 97.5% -30.0
	Estimation Comments	[Not specified]

Statistical Analysis 8 for Number of Subjects With Culture-confirmed Influenza Illness Caused by Non-Vaccine Like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for B strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.319
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	51.7
	Confidence Interval	(1-Sided) 97.5% 19.4
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains
Measure Description	The vaccine efficacy of CCI and IVV vaccines was estimated relative to placebo as the number of subjected prevented against virus-confirmed symptomatic influenza A or B illness caused by vaccine-like and non-vaccine-like strains.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was done on PP efficacy population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	3776	3638	3843
Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains [units: Subjects]			
Overall	42	49	140
A/H3N2	6	12	25
A/H1N1	6	10	57

	CCI Vaccine	IVV Vaccine	Placebo
B	30	27	61

Statistical Analysis 1 for Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo (Overall) Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	69.5
	Confidence Interval	(1-Sided) 97.5% 55.0
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for A/H1N1 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	89.3
	Confidence Interval	(1-Sided) 97.5% 73.0
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for A/H3N2 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.040
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	75.6
	Confidence Interval	(1-Sided) 97.5% 35.1
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	CCI Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of CCI vaccine vs. Placebo for B strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of CCI vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.37
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of CCI vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	49.9
	Confidence Interval	(1-Sided) 97.5% 18.2
	Estimation Comments	[Not specified]

Statistical Analysis 5 for Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo (Overall) Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.003

	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	63.0
	Confidence Interval	(1-Sided) 97.5% 46.7
	Estimation Comments	[Not specified]

Statistical Analysis 6 for Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for A/H1N1 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	81.5
	Confidence Interval	(1-Sided) 97.5% 60.9
	Estimation Comments	[Not specified]

Statistical Analysis 7 for Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for A/H3N2 strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.53
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.
	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	49.3
	Confidence Interval	(1-Sided) 97.5% - 9.0
	Estimation Comments	[Not specified]

Statistical Analysis 8 for Number of Subjects With Influenza Caused by Vaccine-like and Non-vaccine-like Strains

Statistical Analysis Overview	Comparison Groups	IVV Vaccine, Placebo
	Comments	Vaccine efficacy (VE) of IVV vaccine vs. Placebo for B strain Simultaneous one-sided 97.5% confidence interval (CI) for the VE of IVV vaccine relative to Placebo was based on the Sidak-corrected score CIs for the two relative risks.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.26
	Comments	Adjusted p-values are from score statistic with Sidak correction testing the null hypothesis that the VE of IVV vs. placebo is <= 40% (the relative risk, >= 0.60). If adjusted p-value is <0.025, then the comparison is statistically significant.

	Method	Other [Sidak-corrected score CI]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Vaccine Efficacy]
	Estimated Value	53.2
	Confidence Interval	(1-Sided) 97.5% 22.2
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Influenza-Associated Days in Bed, All Subjects
Measure Description	The number of subjects in this analysis included all subjects in the per protocol efficacy population.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was done on the PP efficacy population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	3775	3638	3837
Influenza-Associated Days in Bed, All Subjects [units: Number of Days] Mean (Standard Deviation)	0.04 (0.496)	0.04 (0.404)	0.12 (0.777)

5. Secondary Outcome Measure:

Measure Title	Influenza-Associated Days in Bed, Subset of Subjects With Virus-Confirmed- Influenza
Measure Description	The analysis was done among the subset of subjects in the per protocol efficacy population who had culture-confirmed influenza.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was done on PP efficacy population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	180	230	332
Influenza-Associated Days in Bed, Subset of Subjects With Virus-Confirmed- Influenza [units: Number of Days] Mean (Standard Deviation)	3.9 (2.62)	2.9 (1.98)	3.4 (2.4)

6. Secondary Outcome Measure:

Measure Title	Number Of Medical Visits (Inpatient and Outpatient) Due to Influenza Illness or Symptoms of Influenza, All Subjects
Measure Description	The number of subjects in this analysis included all subjects in the per protocol efficacy population.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was done of PP efficacy population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	3775	3638	3838
Number Of Medical Visits (Inpatient and Outpatient) Due to Influenza Illness or Symptoms of Influenza, All Subjects [units: Number of Medical Visits] Mean (Standard Deviation)	0.01 (0.138)	0.01 (0.134)	0.03 (0.262)

7. Secondary Outcome Measure:

Measure Title	Number of Medical Visits (Inpatient and Outpatient), Subset of Subjects With Virus-Confirmed-Influenza
Measure Description	The analysis was done among the subset of subjects in the per protocol efficacy population who had culture-confirmed influenza.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was done of PP efficacy population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	180	230	332
Number of Medical Visits (Inpatient and Outpatient), Subset of Subjects With Virus-Confirmed-Influenza [units: Number of Medical Visits] Mean (Standard Deviation)	0.8 (0.92)	0.6 (1.0)	0.8 (1.16)

8. Secondary Outcome Measure:

Measure Title	Number of Days of Usual Activity (i.e. Job, School,Household/Family/Community Activities) Lost Due to Influenza Disease, All Subjects
Measure Description	The number of subjects in this analysis included all subjects in the per protocol efficacy population.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was done on PP efficacy population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	3775	3638	3837
Number of Days of Usual Activity (i.e. Job, School,Household/Family/Community Activities) Lost Due to Influenza Disease, All Subjects [units: Numebr of Days of Usual Activity Lost] Mean (Standard Deviation)	0.06 (0.635)	0.05 (0.605)	0.16 (1.006)

9. Secondary Outcome Measure:

Measure Title	Number of Days of Usual Activity (i.e. Job, School,Household/Family/Community Activities) Lost, Subset of Subjects With Virus-Confirmed-Influenza
Measure Description	The analysis was done among the subset of subjects in the per protocol efficacy population who had culture-confirmed influenza.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Analysis was done on PP efficacy population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	180	230	332
Number of Days of Usual Activity (i.e. Job, School,Household/Family/Community Activities) Lost, Subset of Subjects With Virus-Confirmed-Influenza [units: Numebr of Days of Usual Activity Lost] Mean (Standard Deviation)	5.1 (3.41)	4.0 (3.4)	4.6 (3.45)

10. Secondary Outcome Measure:

Measure Title	Percentages of Subjects Who Achieved HI Titers ≥40 After One Vaccination of Either Cell-culture Derived or Egg-derived Influenza Vaccine or Placebo
Measure Description	Immunogenicity was measured as the percentage of subjects achieving HI titers ≥40 at baseline (day 1) and three weeks after (day 22) one vaccination of either cell-culture or egg-derived vaccine or placebo for each of the three influenza vaccine strains (A/H1N1, A/H3N2 and B), evaluated using hemagglutination inhibition (HI) egg-derived antigen assay. This criterion is met according to US (CBER) guideline if the lower limit of the two-sided 95% CI for the percentage of subjects achieving HI titers ≥40 is ≥70%.

Time Frame	Before vaccination (day 1) and three weeks after vaccination (day 22)
Safety Issue?	No

Analysis Population Description

Analysis was done on a subset of subjects who constituted the PP immunogenicity population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	228	695	55
Percentages of Subjects Who Achieved HI Titers ≥40 After One Vaccination of Either Cell-culture Derived or Egg-derived Influenza Vaccine or Placebo [units: Percentages of subjects] Number (95% Confidence Interval)			
A/H1N1 - Day 1	48 (42 to 55)	53 (49 to 57)	60 (46 to 73)
A/H1N1 - Day 22	99 (97 to 100)	98 (97 to 99)	60 (46 to 73)
A/H3N2 - Day 1	63 (57 to 69)	58 (54 to 61)	71 (57 to 82)
A/H3N2 - Day 22	99 (97 to 100)	99 (98 to 100)	65 (51 to 78)
B - Day 1	25 (20 to 31)	23 (20 to 27)	22 (12 to 35)
B - Day 22	78 (72 to 83)	92 (90 to 94)	22 (12 to 35)

11. Secondary Outcome Measure:

Measure Title	Percentages of Subjects Achieving Seroconversion After One Vaccination of Either Cell-culture Derived or Egg-derived Influenza Vaccine or Placebo

Measure Description	As per the CBER guideline, seroconversion is defined as the percentage of subjects with a prevaccination HI titer <10, a postvaccination titer ≥40; or in subjects with prevaccination HI titer ≥10, a ≥4-fold increase in postvaccination HI antibody titer. According to CBER criteria, the lower limit of the two-sided 95% CI for the percentage of subjects achieving seroconversion for HI antibody titer at day 22 met exceeded 40%.
Time Frame	Three weeks after vaccination (day 22)
Safety Issue?	No

Analysis Population Description

Analysis was done on a subset of subjects who constituted the PP immunogenicity population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	228	695	55
Percentages of Subjects Achieving Seroconversion After One Vaccination of Either Cell-culture Derived or Egg-derived Influenza Vaccine or Placebo [units: Percentages of subjects] Number (95% Confidence Interval)			
A/H1N1	78 (72 to 83)	75 (71 to 78)	0 (0 to 6)
A/H3N2	59 (53 to 66)	68 (64 to 71)	0 (0 to 6)
B	51 (45 to 58)	68 (65 to 72)	0 (0 to 6)

12. Secondary Outcome Measure:

Measure Title	Number of Subjects Reported Solicited Local and Systemic Reactions up to 7 Days After Vaccination
Measure Description	The solicited local and systemic reactogenicity were collected up to 7 days after vaccination for all three vaccine groups.
Time Frame	Up to 7 days post vaccination

Safety Issue?	Yes

Analysis Population Description

Analysis was done on Safety population i.e. all subjects in the exposed population who provide post vaccination safety data.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Measured Values

	CCI Vaccine	IVV Vaccine	Placebo
Number of Participants Analyzed	3813	3669	3894
Number of Subjects Reported Solicited Local and Systemic Reactions up to 7 Days After Vaccination [units: Subjects]			
Injection site Pain (N=3813, 3668, 3894)	1158	893	375
Injection site Erythema (N=3813, 3668, 3894)	510	492	391
Injection site Induration (N=3813,3668,3894)	239	207	101
Injection site Ecchymosis (N=3813, 3668, 3894)	143	110	147
Injection site Swelling (N=3813, 3667, 3894)	218	181	103
Chills	210	211	223
Malaise (N=3813, 3669, 3893)	290	259	237
Myalgia (N=3813, 3669, 3893)	450	364	275
Arthralgia (N=3813, 3669, 3893)	108	111	125
Headache (N=3813, 3669, 3893)	564	551	592
Sweating (N=3812, 3669, 3893)	124	122	120
Fatigue (N=3812, 3669, 3893)	390	404	384
Fever (>= 38 C)	27	21	15
Oral Temp. (< 38 C)	3786	3648	3879

	CCI Vaccine	IVV Vaccine	Placebo
Stayed home due to Reactions (N=3781, 3651, 3867)	42	62	42
Analgesic medicines used (N=3810, 3665, 3892)	394	397	386

Reported Adverse Events

Time Frame	Serious Adverse Events were collected throughout the study period (i.e., 6 months).
Additional Description	The analysis was done on the safety population.

Reporting Groups

	Description
CCI Vaccine	One dose of cell culture-derived influenza vaccine.
IVV Vaccine	One dose of the trivalent egg-derived influenza virus vaccine.
Placebo	One dose of phosphate buffered solution (PBS).

Serious Adverse Events

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	42/3813 (1.1%)		35/3669 (0.95%)		38/3894 (0.98%)	
Cardiac disorders						
Cardiac Failure Congestive [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Coronary Artery disease [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Ear and labyrinth disorders						
Vertigo Positional [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Endocrine disorders						

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Hyperthyroidism [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Eye disorders						
Mydriasis [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Gastrointestinal disorders						
Abdominal Pain [A] †	1/3813 (0.03%)	1	1/3669 (0.03%)	1	0/3894 (0%)	0
Abdominal Pain Upper [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	1/3894 (0.03%)	1
Anal Fistula [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Colitis Ischaemic [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Crohn's Disease [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Gastrooesophageal Reflux Disease [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Haemorrhoids [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Inguinal Hernia [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	1/3894 (0.03%)	1
Intestinal Obstructon [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Pancreatitis Acute [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Peritoneal Cyst [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Salivary Duct Inflammation [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Salivary Gland Calculus [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Small Intestinal Obstruction [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Vomiting in Pregnancy [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
General disorders						
Chest Pain [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Death [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Non-Cardiac Chest Pain [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Hepatobiliary disorders						
Cholangitis Sclerosing [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Cholecystitis [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Cholecystitis Acute [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Cholelithiasis [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	1/3894 (0.03%)	1
Hepatitis Acute [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Jaundice [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Infections and infestations						
Acute Sinusitis [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Acute Tonsillitis [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Appendicitis [A] †	1/3813 (0.03%)	1	1/3669 (0.03%)	1	3/3894 (0.08%)	3
Breast Cellulitis [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Cellulitis [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Diverticulitis [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Gastroenteritis Viral [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Infection [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Lung Abscess [A] †	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Mastitis Bacterial [A] †	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Perirectal Abscess [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Peritonsillar Abscess [A] †	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Pharyngitis [A] *	0/3813 (0%)	0	0/3669 (0%)	0	2/3894 (0.05%)	2
Pneumonia [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	2/3894 (0.05%)	2
Pyelonephritis Acute [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Urinary Tract Infection [A] *	1/3813 (0.03%)	1	1/3669 (0.03%)	1	0/3894 (0%)	0
Wound Infection [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Injury, poisoning and procedural complications						

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Abdominal Injury [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Alcohol Poisoning [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Ankle Fracture [A] *	2/3813 (0.05%)	2	0/3669 (0%)	0	1/3894 (0.03%)	1
Chest Injury [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Extradural Haematoma [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Foot Fracture [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Joint Injury [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Road Traffic Accident [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Skull Fracture [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Subdural Haematoma [A] *	1/3813 (0.03%)	1	1/3669 (0.03%)	1	0/3894 (0%)	0
Tendon Rupture [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Upper Limb Fracture [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Wound [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Metabolism and nutrition disorders						
Obesity [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Musculoskeletal and connective tissue disorders						

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Back Pain [A] *	0/3813 (0%)	0	0/3669 (0%)	0	2/3894 (0.05%)	2
Intervertebral Disc Protrusion [A] *	2/3813 (0.05%)	2	0/3669 (0%)	0	2/3894 (0.05%)	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Adenocarcinoma of the Cervix [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Bone Neoplasm [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Breast Cancer [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Carcinoid Tumour [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Leiomyosarcoma [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Ovarian Cancer [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Nervous system disorders						
Cerebral Haemorrhage [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Epilepsy [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Headache [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Loss of Consciousness [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Migraine [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	1/3894 (0.03%)	1
Syncope [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Tethered Cord Syndrome [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Pregnancy, puerperium and perinatal conditions						
Abortion Spontaneous [A] *	1/3813 (0.03%)	1	1/3669 (0.03%)	1	0/3894 (0%)	0
Delivery [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Ectopic Pregnancy [A] *	1/3813 (0.03%)	1	1/3669 (0.03%)	1	0/3894 (0%)	0
Psychiatric disorders						
Acute Stress Disorder [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Anxiety [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Bipolar Disorder [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Borderline Personality Disorder [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Major Depression [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Psychotic Disorder [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Renal and urinary disorders						
Bladder Prolapse [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Dysuria [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Renal Failure Acute [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Reproductive system and breast disorders						

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Breast Hyperplasia [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Dysmenorrhoea [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Haemorrhagic Ovarian Cyst [A] *	0/3813 (0%)	0	2/3669 (0.05%)	2	0/3894 (0%)	0
Menometrorrhagia [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Pelvic Pain [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Polycystic Ovaries [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Uterine Haemorrhage [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Respiratory, thoracic and mediastinal disorders						
Dyspnoea [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Nasal Septum Deviation [A] *	1/3813 (0.03%)	1	2/3669 (0.05%)	2	0/3894 (0%)	0
Pulmonary Embolism [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Tonsillar Hypertrophy [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Skin and subcutaneous tissue disorders						
Dermatitis Atopic [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1
Social circumstances						
Homicide [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Surgical and medical procedures						

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Aortic Valve Replacement [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Appendicetomy [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	1/3894 (0.03%)	1
Knee Operation [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Medical Device Removal [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Nasal Septal Operation [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Rhinoplasty [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Tendon Operation [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Vascular disorders						
Deep Vein Thrombosis [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Hypertension [A] *	1/3813 (0.03%)	1	0/3669 (0%)	0	0/3894 (0%)	0
Thrombophlebitis [A] *	0/3813 (0%)	0	1/3669 (0.03%)	1	0/3894 (0%)	0
Varicose Vein [A] *	0/3813 (0%)	0	0/3669 (0%)	0	1/3894 (0.03%)	1

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	CCI Vaccine		IVV Vaccine		Placebo	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	1949/3813 (51.11%)		1703/3669 (46.42%)		1387/3894 (35.62%)	
General disorders						
Chills [A] †	212/3813 (5.56%)		212/3669 (5.78%)		225/3894 (5.78%)	
Fatigue [A] †	390/3813 (10.23%)		404/3669 (11.01%)		386/3894 (9.91%)	
Injection Site Erythema [A] †	510/3813 (13.38%)		492/3669 (13.41%)		391/3894 (10.04%)	
Injection Site Induration [A] †	239/3813 (6.27%)		207/3669 (5.64%)		101/3894 (2.59%)	
Injection Site Pain [A] †	1158/3813 (30.37%)		893/3669 (24.34%)		375/3894 (9.63%)	
Injection Site Swelling [A] †	218/3813 (5.72%)		181/3669 (4.93%)		103/3894 (2.65%)	
Malaise [A] †	290/3813 (7.61%)		260/3669 (7.09%)		238/3894 (6.11%)	
Musculoskeletal and connective tissue disorders						
Myalgia [A] †	451/3813 (11.83%)		369/3669 (10.06%)		278/3894 (7.14%)	
Nervous system disorders						
Headache [A] †	571/3813 (14.98%)		554/3669 (15.1%)		597/3894 (15.33%)	

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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