Clinical trial results:
Safety and Immunogenicity of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine Adsorbed (SP0173) in Healthy Adolescents, Adults, and Older Adults

Summary

EudraCT number	2018-003838-32
Trial protocol	Outside EU/EEA
Global end of trial date	21 February 2017

Results information

Result version number	v1 (current)
This version publication date	30 May 2019
First version publication date	30 May 2019

Trial information

Trial identification

Sponsor protocol code	ADC01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02587520
WHO universal trial number (UTN)	U1111-1161-3027

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc.
Sponsor organisation address	1 Discovery Drive, Swiftwater, United States, 18370
Public contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 May 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 February 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety profile of each SP0173 investigational formulations.
To describe the immunogenicity of each SP0173 investigational formulations.

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment was also available on site in case of any immediate adverse reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 October 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1363
Worldwide total number of subjects	1363
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	383
Adolescents (12-17 years)	70
Adults (18-64 years)	455
From 65 to 84 years	449
85 years and over	6

Subject disposition

Recruitment

Recruitment details:

Study subjects were enrolled in 20 centers in the Unites States (US) from 22 October 2015 to 15 August 2016.

Pre-assignment

Screening details:

A total of 1363 subjects were randomized in a 1:1:1 ratio to 1 of the 6 formulation study groups. Randomization was stratified by age (adolescents: age 10–18 years, adults: age 19–64 years, older adults: age >= 65 years).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Adolescents: SP0173 Formulation 1

Arm description:

Healthy subjects aged 10–18 years received a single dose of the SP0173 Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine Adsorbed (Tdap) vaccine.

Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap: Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 milliliter (mL), intramuscular, single dose on Day 0.

Arm title	Adolescents: SP0173 Formulation 2

Arm description:

Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.

Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Adolescents: SP0173 Formulation 3

Arm description:

Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.

Arm type	Experimental

Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Adolescents: SP0173 Formulation 4

Arm description:

Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.

Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Adolescents: Adacel®

Arm description:

Healthy subjects aged 10–18 years received Adacel®.

Arm type	Active comparator
Investigational medicinal product name	Adacel®
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Adolescents: Boostrix®

Arm description:

Healthy subjects aged 10–18 years received Boostrix®.

Arm type	Active comparator
Investigational medicinal product name	Boostrix®
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Adults: SP0173 Formulation 1

Arm description:

Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.

Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:
0.5 mL, intramuscular, single dose on Day 0.

Arm title	Adults: SP0173 Formulation 2
Arm description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL, intramuscular, single dose on Day 0.	
Arm title	Adults: SP0173 Formulation 3
Arm description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL, intramuscular, single dose on Day 0.	
Arm title	Adults: SP0173 Formulation 4
Arm description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL, intramuscular, single dose on Day 0.	
Arm title	Adults: Adacel®
Arm description:	
Healthy subjects aged 19–64 years received Adacel®.	
Arm type	Active comparator
Investigational medicinal product name	Adacel®
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL, intramuscular, single dose on Day 0.	
Arm title	Adults: Boostrix®

Arm description:	
Healthy subjects aged 19–64 years received Boostrix®.	
Arm type	Active comparator
Investigational medicinal product name	Boostrix®
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL, intramuscular, single dose on Day 0.	
Arm title	Older Adults: SP0173 Formulation 1
Arm description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL, intramuscular, single dose on Day 0.	
Arm title	Older Adults: SP0173 Formulation 2
Arm description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL, intramuscular, single dose on Day 0.	
Arm title	Older Adults: SP0173 Formulation 3
Arm description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Arm type	Experimental
Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL, intramuscular, single dose on Day 0.	
Arm title	Older Adults: SP0173 Formulation 4
Arm description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Arm type	Experimental

Investigational medicinal product name	SP0173
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Older Adults: Adacel®

Arm description:

Healthy subjects aged >= 65 years received Adacel®.

Arm type	Active comparator
Investigational medicinal product name	Adacel®
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Older Adults: Boostrix®

Arm description:

Healthy subjects aged >= 65 years received Boostrix®.

Arm type	Active comparator
Investigational medicinal product name	Boostrix®
Investigational medicinal product code	
Other name	Tdap
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Number of subjects in period 1	Adolescents: SP0173 Formulation 1	Adolescents: SP0173 Formulation 2	Adolescents: SP0173 Formulation 3
Started	80	71	78
Completed	78	69	77
Not completed	2	2	1
Consent withdrawn by subject	-	-	1
Adverse event	-	-	-
Lost to follow-up	-	2	-
Protocol deviation	2	-	-

Number of subjects in period 1	Adolescents: SP0173 Formulation 4	Adolescents: Adacel®	Adolescents: Boostrix®
Started	79	75	75
Completed	74	75	72
Not completed	5	0	3
Consent withdrawn by subject	1	-	1

Adverse event	-	-	-
Lost to follow-up	2	-	1
Protocol deviation	2	-	1

Number of subjects in period 1	Adults: SP0173 Formulation 1	Adults: SP0173 Formulation 2	Adults: SP0173 Formulation 3
Started	76	73	76
Completed	73	71	73
Not completed	3	2	3
Consent withdrawn by subject	1	-	-
Adverse event	-	-	-
Lost to follow-up	1	1	-
Protocol deviation	1	1	3

Number of subjects in period 1	Adults: SP0173 Formulation 4	Adults: Adacel®	Adults: Boostrix®
Started	76	76	73
Completed	71	73	69
Not completed	5	3	4
Consent withdrawn by subject	-	-	-
Adverse event	-	-	1
Lost to follow-up	2	2	1
Protocol deviation	3	1	2

Number of subjects in period 1	Older Adults: SP0173 Formulation 1	Older Adults: SP0173 Formulation 2	Older Adults: SP0173 Formulation 3
Started	77	74	78
Completed	77	73	78
Not completed	0	1	0
Consent withdrawn by subject	-	1	-
Adverse event	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Older Adults: SP0173 Formulation 4	Older Adults: Adacel®	Older Adults: Boostrix®
Started	72	76	78
Completed	72	76	78
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Adverse event	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	Adolescents: SP0173 Formulation 1
Reporting group description:	
Healthy subjects aged 10–18 years received a single dose of the SP0173 Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine Adsorbed (Tdap) vaccine.	
Reporting group title	Adolescents: SP0173 Formulation 2
Reporting group description:	
Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adolescents: SP0173 Formulation 3
Reporting group description:	
Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adolescents: SP0173 Formulation 4
Reporting group description:	
Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adolescents: Adacel®
Reporting group description:	
Healthy subjects aged 10–18 years received Adacel®.	
Reporting group title	Adolescents: Boostrix®
Reporting group description:	
Healthy subjects aged 10–18 years received Boostrix®.	

Reporting group title	Adults: SP0173 Formulation 1
Reporting group description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adults: SP0173 Formulation 2
Reporting group description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adults: SP0173 Formulation 3
Reporting group description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adults: SP0173 Formulation 4
Reporting group description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adults: Adacel®
Reporting group description:	
Healthy subjects aged 19–64 years received Adacel®.	
Reporting group title	Adults: Boostrix®
Reporting group description:	
Healthy subjects aged 19–64 years received Boostrix®.	
Reporting group title	Older Adults: SP0173 Formulation 1
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 2
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 3
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 4

Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: Adacel®
Reporting group description:	
Healthy subjects aged >= 65 years received Adacel®.	
Reporting group title	Older Adults: Boostrix®
Reporting group description:	
Healthy subjects aged >= 65 years received Boostrix®.	

Reporting group values	Adolescents: SP0173 Formulation 1	Adolescents: SP0173 Formulation 2	Adolescents: SP0173 Formulation 3
Number of subjects	80	71	78
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	10.8	11.0	11.1
standard deviation	± 1.3	± 1.3	± 1.6
Gender categorical Units: Subjects			
Female	41	33	35
Male	39	38	43
Race Units: Subjects			
White	71	60	71
Asian	0	0	1
Black or African American	7	9	2
American Indian or Alaska Native	0	1	0
Native Hawaiian or other Pacific Islander	0	0	1
Mixed origin	2	1	3
Missing	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	4	2	3
Not Hispanic or Latino	76	69	75
Missing	0	0	0

Reporting group values	Adolescents: SP0173 Formulation 4	Adolescents: Adacel®	Adolescents: Boostrix®
Number of subjects	79	75	75
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	10.8	10.8	11.1
standard deviation	± 1.4	± 1.5	± 1.6

Gender categorical Units: Subjects			
Female	37	39	40
Male	42	36	35
Race Units: Subjects			
White	72	63	65
Asian	0	2	2
Black or African American	4	8	4
American Indian or Alaska Native	0	0	0
Native Hawaiian or other Pacific Islander	1	0	0
Mixed origin	2	2	4
Missing	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	4	4	6
Not Hispanic or Latino	75	71	69
Missing	0	0	0

Reporting group values	Adults: SP0173 Formulation 1	Adults: SP0173 Formulation 2	Adults: SP0173 Formulation 3
Number of subjects	76	73	76
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	42.5	41.2	40.1
standard deviation	± 12.5	± 12.1	± 12.8
Gender categorical Units: Subjects			
Female	43	46	38
Male	33	27	38
Race Units: Subjects			
White	48	51	46
Asian	2	1	4
Black or African American	23	18	24
American Indian or Alaska Native	1	1	0
Native Hawaiian or other Pacific Islander	0	1	0
Mixed origin	2	1	2
Missing	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	17	19	8
Not Hispanic or Latino	59	54	68
Missing	0	0	0

Reporting group values	Adults: SP0173 Formulation 4	Adults: Adacel®	Adults: Boostrix®
Number of subjects	76	76	73

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	42.1	41.3	42.5
standard deviation	± 13.0	± 12.7	± 13.2
Gender categorical Units: Subjects			
Female	39	44	36
Male	37	32	37
Race Units: Subjects			
White	53	52	51
Asian	1	0	1
Black or African American	18	23	19
American Indian or Alaska Native	3	0	1
Native Hawaiian or other Pacific Islander	0	0	0
Mixed origin	1	1	1
Missing	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	11	15	10
Not Hispanic or Latino	65	61	63
Missing	0	0	0

Reporting group values	Older Adults: SP0173 Formulation 1	Older Adults: SP0173 Formulation 2	Older Adults: SP0173 Formulation 3
Number of subjects	77	74	78
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	71.3	71.8	70.9
standard deviation	± 5.4	± 5.4	± 4.8
Gender categorical Units: Subjects			
Female	37	38	51
Male	40	36	27
Race Units: Subjects			
White	69	64	70
Asian	0	0	0
Black or African American	7	8	8
American Indian or Alaska Native	0	1	0
Native Hawaiian or other Pacific Islander	0	0	0
Mixed origin	1	1	0
Missing	0	0	0

Ethnicity Units: Subjects			
Hispanic or Latino	11	12	13
Not Hispanic or Latino	64	59	64
Missing	2	3	1

Reporting group values	Older Adults: SP0173 Formulation 4	Older Adults: Adacel®	Older Adults: Boostrix®
Number of subjects	72	76	78
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	70.8	70.9	71.3
standard deviation	± 5.1	± 5.0	± 4.8
Gender categorical Units: Subjects			
Female	38	46	45
Male	34	30	33
Race Units: Subjects			
White	66	69	68
Asian	1	1	0
Black or African American	5	6	10
American Indian or Alaska Native	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Mixed origin	0	0	0
Missing	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	15	12	13
Not Hispanic or Latino	55	63	61
Missing	2	1	4

Reporting group values	Total		
Number of subjects	1363		
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	726		
Male	637		

Race Units: Subjects			
White	1109		
Asian	16		
Black or African American	203		
American Indian or Alaska Native	8		
Native Hawaiian or other Pacific Islander	3		
Mixed origin	24		
Missing	0		
Ethnicity Units: Subjects			
Hispanic or Latino	179		
Not Hispanic or Latino	1171		
Missing	13		

End points

End points reporting groups

Reporting group title	Adolescents: SP0173 Formulation 1
Reporting group description:	
Healthy subjects aged 10–18 years received a single dose of the SP0173 Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine Adsorbed (Tdap) vaccine.	
Reporting group title	Adolescents: SP0173 Formulation 2
Reporting group description:	
Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adolescents: SP0173 Formulation 3
Reporting group description:	
Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adolescents: SP0173 Formulation 4
Reporting group description:	
Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adolescents: Adacel®
Reporting group description:	
Healthy subjects aged 10–18 years received Adacel®.	
Reporting group title	Adolescents: Boostrix®
Reporting group description:	
Healthy subjects aged 10–18 years received Boostrix®.	

Reporting group title	Adults: SP0173 Formulation 1
Reporting group description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adults: SP0173 Formulation 2
Reporting group description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adults: SP0173 Formulation 3
Reporting group description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adults: SP0173 Formulation 4
Reporting group description:	
Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Adults: Adacel®
Reporting group description:	
Healthy subjects aged 19–64 years received Adacel®.	
Reporting group title	Adults: Boostrix®
Reporting group description:	
Healthy subjects aged 19–64 years received Boostrix®.	
Reporting group title	Older Adults: SP0173 Formulation 1
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 2
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 3
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 4

Reporting group description:

Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.

Reporting group title	Older Adults: Adacel®

Reporting group description:

Healthy subjects aged >= 65 years received Adacel®.

Reporting group title	Older Adults: Boostrix®

Reporting group description:

Healthy subjects aged >= 65 years received Boostrix®.

Primary: Percentage of Subjects With Solicited Injections Site or Systemic Reactions Following Vaccination at Day 0: Aged 10–18 Years

End point title	Percentage of Subjects With Solicited Injections Site or Systemic Reactions Following Vaccination at Day 0: Aged 10–18 Years[1][2]

End point description:

A solicited reaction is an adverse event (AE) that is prelisted in the electronic Case Report Form (eCRF) & considered to be related to vaccination. A solicited reaction is therefore an adverse drug reaction (ADR) observed & reported under the conditions (nature & onset) prelisted (i.e., solicited) in the eCRF. An unsolicited AE is an observed AE that does not fulfill the conditions prelisted in the eCRF in terms of symptom and/or onset post-vaccination. Solicited injection site reactions: Pain, Erythema, Swelling, Upper limb edema, Extensive limb swelling & solicited systemic reactions: Fever, Headache, Malaise, Myalgia. Percentages of subjects with at least one solicited injection site reactions & systemic reactions were reported. Safety analysis set that was defined as those subjects who had received study vaccine. All subjects had their safety analyzed according to the vaccine they actually received. Here, "n"= number of subjects with available data for this endpoint.

End point type	Primary

End point timeframe:

Within 7 days after vaccination

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical hypothesis was tested.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Arms applicable for this endpoint are reported.

End point values	Adolescents: SP0173 Formulation 1	Adolescents: SP0173 Formulation 2	Adolescents: SP0173 Formulation 3	Adolescents: SP0173 Formulation 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	79	71	77	77
Units: percentage of subjects				
number (not applicable)				
Pain (n= 78, 69, 77, 74, 75, 73)	75.6	73.9	64.9	66.2
Erythema (n= 78, 69, 77, 74, 75, 73)	11.5	5.8	13.0	1.4
Swelling (n= 78, 69, 77, 74, 75, 73)	9.0	5.8	10.4	0.0
Upper limb edema (n= 77, 69, 77, 74, 74, 73)	58.4	59.4	63.6	62.2
Extensive limb swelling (n= 79, 71, 77, 75, 75)	0.0	0.0	0.0	0.0
Fever (n= 77, 69, 77, 74, 75, 73)	1.3	0.0	1.3	0.0
Headache (n= 78, 69, 77, 74, 75, 73)	26.9	20.3	24.7	33.8
Malaise (n= 78, 69, 77, 74, 75, 73)	17.9	24.6	18.2	24.3
Myalgia (n= 78, 69, 77, 74, 75, 73)	53.8	50.7	49.4	56.8

End point values	Adolescents: Adacel®	Adolescents: Boostrix®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	75		
Units: percentage of subjects				
number (not applicable)				
Pain (n= 78, 69, 77, 74, 75, 73)	78.7	65.8		
Erythema (n= 78, 69, 77, 74, 75, 73)	5.3	2.7		
Swelling (n= 78, 69, 77, 74, 75, 73)	1.3	5.5		
Upper limb edema (n= 77, 69, 77, 74, 74, 73)	64.9	45.2		
Extensive limb swelling (n= 79, 71, 77, 75, 75)	0.0	0.0		
Fever (n= 77, 69, 77, 74, 75, 73)	0.0	1.4		
Headache (n= 78, 69, 77, 74, 75, 73)	26.7	37.0		
Malaise (n= 78, 69, 77, 74, 75, 73)	16.0	23.3		
Myalgia (n= 78, 69, 77, 74, 75, 73)	69.3	52.1		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Solicited Injections Site or Systemic Reactions Following Vaccination at Day 0: Aged 19–64 Years

End point title	Percentage of Subjects With Solicited Injections Site or Systemic Reactions Following Vaccination at Day 0: Aged 19–64 Years[3][4]

End point description:

A solicited reaction is an AE that is prelisted in the eCRF and considered to be related to vaccination. A solicited reaction is therefore an ADR observed and reported under the conditions (nature and onset) prelisted (i.e., solicited) in the eCRF. An unsolicited AE is an observed AE that does not fulfill the conditions prelisted in the eCRF in terms of symptom and/or onset post-vaccination. Solicited injection site reactions: Pain, Erythema, Swelling, Upper limb edema, Extensive limb swelling and systemic reactions: Fever, Headache, Malaise, Myalgia. Percentages of subjects with at least one solicited injection site reactions and systemic reactions were reported. Analysis was performed on safety analysis set. Here, "n"= number of subjects with available data for this endpoint.

End point type	Primary

End point timeframe:

Within 7 days after vaccination

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical hypothesis was tested.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Arms applicable for this endpoint are reported.

End point values	Adults: SP0173 Formulation 1	Adults: SP0173 Formulation 2	Adults: SP0173 Formulation 3	Adults: SP0173 Formulation 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	76	73	76	76
Units: percentage of subjects				
number (not applicable)				
Pain (n= 73, 70, 73, 71, 72, 68)	52.1	48.6	67.1	59.2
Erythema (n= 73, 70, 73, 71, 72, 68)	2.7	1.4	2.7	0.0
Swelling (n= 73, 70, 73, 71, 72, 68)	1.4	4.3	5.5	1.4
Upper limb edema (n= 71, 67, 72, 69, 71, 67)	39.4	55.2	56.9	53.6
Extensive limb swelling (n= 76, 73, 76, 76, 76, 72	0.0	0.0	0.0	0.0
Fever (n= 71, 68, 72, 70, 71, 68)	0.0	0.0	0.0	0.0
Headache (n= 73, 71, 73, 71, 72, 68)	21.9	15.5	26.0	26.8
Malaise (n= 73, 71, 73, 71, 72, 68)	24.7	12.7	21.9	26.8
Myalgia (n= 73, 71, 73, 71, 72, 68)	43.8	40.8	47.9	50.7

End point values	Adults: Adacel®	Adults: Boostrix®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	76	72		
Units: percentage of subjects				
number (not applicable)				
Pain (n= 73, 70, 73, 71, 72, 68)	68.1	51.5		
Erythema (n= 73, 70, 73, 71, 72, 68)	6.9	2.9		
Swelling (n= 73, 70, 73, 71, 72, 68)	4.2	1.5		
Upper limb edema (n= 71, 67, 72, 69, 71, 67)	49.3	46.3		
Extensive limb swelling (n= 76, 73, 76, 76, 76, 72	1.3	0.0		
Fever (n= 71, 68, 72, 70, 71, 68)	2.8	1.5		
Headache (n= 73, 71, 73, 71, 72, 68)	26.4	27.9		
Malaise (n= 73, 71, 73, 71, 72, 68)	31.9	22.1		
Myalgia (n= 73, 71, 73, 71, 72, 68)	54.2	41.2		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Solicited Injections Site or Systemic Reactions Following Vaccination at Day 0: Aged >= 65 Years

End point title	Percentage of Subjects With Solicited Injections Site or Systemic Reactions Following Vaccination at Day 0: Aged >= 65 Years[5][6]

End point description:

A solicited reaction is an AE that is prelisted in the eCRF and considered to be related to vaccination. A solicited reaction is therefore an ADR observed and reported under the conditions (nature and onset) prelisted (i.e., solicited) in the eCRF. An unsolicited AE is an observed AE that does not fulfill the conditions prelisted in the eCRF in terms of symptom and/or onset post-vaccination. Solicited injection

site reactions: Pain, Erythema, Swelling, Upper limb edema, Extensive limb swelling and systemic reactions: Fever, Headache, Malaise, Myalgia. Percentages of subjects with at least one solicited injection site reactions and systemic reactions were reported. Analysis was performed on safety analysis set. Here, "n"= number of subjects with available data for this endpoint.

End point type	Primary

End point timeframe:

Within 7 days after vaccination

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical hypothesis was tested.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Arms applicable for this endpoint are reported.

End point values	Older Adults: SP0173 Formulation 1	Older Adults: SP0173 Formulation 2	Older Adults: SP0173 Formulation 3	Older Adults: SP0173 Formulation 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	73	78	72
Units: percentage of subjects				
number (not applicable)				
Pain (77, 73, 78, 72, 75, 78)	27.3	46.6	43.6	47.2
Erythema (77, 73, 78, 72, 75, 78)	0.0	1.4	2.6	2.8
Swelling (77, 73, 78, 72, 75, 78)	1.3	8.2	7.7	2.8
Upper limb edema (75, 70, 75, 71, 72, 74)	50.7	61.4	48.0	53.5
Extensive limb swelling (77, 73, 78, 72, 76, 78)	0.0	0.0	0.0	0.0
Fever (76, 72, 77, 71, 72, 74)	0.0	1.4	0.0	0.0
Headache (77, 73, 78, 72, 74, 77)	7.8	13.7	25.6	16.7
Malaise (77, 73, 77, 72, 74, 77)	7.8	16.4	18.2	12.5
Myalgia (77, 73, 77, 72, 74, 77)	15.6	28.8	39.0	31.9

End point values	Older Adults: Adacel®	Older Adults: Boostrix®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	76	78		
Units: percentage of subjects				
number (not applicable)				
Pain (77, 73, 78, 72, 75, 78)	37.3	32.1		
Erythema (77, 73, 78, 72, 75, 78)	4.0	1.3		
Swelling (77, 73, 78, 72, 75, 78)	1.3	2.6		
Upper limb edema (75, 70, 75, 71, 72, 74)	44.4	54.1		
Extensive limb swelling (77, 73, 78, 72, 76, 78)	0.0	0.0		
Fever (76, 72, 77, 71, 72, 74)	0.0	0.0		
Headache (77, 73, 78, 72, 74, 77)	14.9	18.2		
Malaise (77, 73, 77, 72, 74, 77)	10.8	7.8		
Myalgia (77, 73, 77, 72, 74, 77)	31.1	22.1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious adverse events (AEs) were collected from Day 0 to Day 7 (solicited reactions) or Day 30 (unsolicited AEs) after vaccination. Serious AEs were collected from Day 0 up to Month 6 after vaccination.

Adverse event reporting additional description:

A SR was an AE that was prelisted (i.e. solicited) in the eCRF and considered to be related to vaccination (adverse drug reaction). An unsolicited AE was an observed AE that did not fulfill the conditions prelisted in the eCRF (i.e.,solicited) in terms of symptom and/or onset post-vaccination. AEs were summarized in the Safety Analysis Set.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Adolescents: SP0173 Formulation 1

Reporting group description:

Healthy subjects aged 10–18 years received a single dose of the SP0173 Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine Adsorbed (Tdap) vaccine.

Reporting group title	Adolescents: SP0173 Formulation 2

Reporting group description:

Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.

Reporting group title	Adolescents: SP0173 Formulation 3

Reporting group description:

Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.

Reporting group title	Adolescents: SP0173 Formulation 4

Reporting group description:

Healthy subjects aged 10–18 years received a single dose of the SP0173 Tdap vaccine.

Reporting group title	Adolescents: Adacel®

Reporting group description:

Healthy subjects aged 10–18 years received Adacel®.

Reporting group title	Adolescents: Boostrix®

Reporting group description:

Healthy subjects aged 10–18 years received Boostrix®.

Reporting group title	Adults: SP0173 Formulation 1

Reporting group description:

Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.

Reporting group title	Adults: SP0173 Formulation 2

Reporting group description:

Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.

Reporting group title	Adults: SP0173 Formulation 3

Reporting group description:

Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.

Reporting group title	Adults: SP0173 Formulation 4

Reporting group description:

Healthy subjects aged 19–64 years received a single dose of the SP0173 Tdap vaccine.

Reporting group title	Adults: Adacel®

Reporting group description:

Healthy subjects aged 19–64 years received Adacel®.

Reporting group title	Adults: Boostrix®

Reporting group description:	
Healthy subjects aged 19–64 years received Boostrix®.	
Reporting group title	Older Adults: SP0173 Formulation 1
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 2
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 3
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: SP0173 Formulation 4
Reporting group description:	
Healthy subjects aged >= 65 years received a single dose of the SP0173 Tdap vaccine.	
Reporting group title	Older Adults: Adacel®
Reporting group description:	
Healthy subjects aged >= 65 years received Adacel®.	
Reporting group title	Older Adults: Boostrix®
Reporting group description:	
Healthy subjects aged >= 65 years received Boostrix®.	

Serious adverse events	Adolescents: SP0173 Formulation 1	Adolescents: SP0173 Formulation 2	Adolescents: SP0173 Formulation 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer Recurrent			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Humerus Fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			

subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Stenosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac Failure Congestive			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Fibrillation			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Embolic Cerebral Infarction			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Device Dislocation			

subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Withdrawal Syndrome			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Post-Traumatic Stress Disorder			

subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 71 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adolescents: SP0173 Formulation 4	Adolescents: Adacel®	Adolescents: Boostrix®
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 77 (1.30%)	0 / 75 (0.00%)	0 / 75 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer Recurrent			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Humerus Fracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	1 / 77 (1.30%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Stenosis			

subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac Failure Congestive			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Fibrillation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Embolic Cerebral Infarction			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Device Dislocation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Withdrawal Syndrome			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Post-Traumatic Stress Disorder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 77 (0.00%)	0 / 75 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adults: SP0173 Formulation 1	Adults: SP0173 Formulation 2	Adults: SP0173 Formulation 3
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 76 (1.32%)	1 / 73 (1.37%)	1 / 76 (1.32%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer Recurrent			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Humerus Fracture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Stenosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac Failure Congestive			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			

subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Fibrillation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Embolic Cerebral Infarction			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Device Dislocation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Withdrawal Syndrome			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 76 (0.00%)	1 / 73 (1.37%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	1 / 76 (1.32%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Post-Traumatic Stress Disorder			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adults: SP0173 Formulation 4	Adults: Adacel®	Adults: Boostrix®
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 76 (1.32%)	0 / 76 (0.00%)	2 / 72 (2.78%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer Recurrent			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Humerus Fracture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Stenosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac Failure Congestive			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Fibrillation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Embolic Cerebral Infarction			

subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Device Dislocation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Withdrawal Syndrome			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Post-Traumatic Stress Disorder			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Older Adults: SP0173 Formulation 1	Older Adults: SP0173 Formulation 2	Older Adults: SP0173 Formulation 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 77 (0.00%)	3 / 73 (4.11%)	4 / 78 (5.13%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer Recurrent			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Humerus Fracture			
subjects affected / exposed	0 / 77 (0.00%)	1 / 73 (1.37%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Stenosis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 73 (1.37%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac Failure Congestive			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 77 (0.00%)	1 / 73 (1.37%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Fibrillation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Embolic Cerebral Infarction			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			

subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Device Dislocation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Withdrawal Syndrome			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			

subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Post-Traumatic Stress Disorder			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Older Adults: SP0173 Formulation 4	Older Adults: Adacel®	Older Adults: Boostrix®
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 72 (1.39%)	2 / 76 (2.63%)	2 / 78 (2.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer Recurrent			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Humerus Fracture			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			

subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Stenosis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac Failure Congestive			
subjects affected / exposed	0 / 72 (0.00%)	1 / 76 (1.32%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Fibrillation			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Embolic Cerebral Infarction			
subjects affected / exposed	0 / 72 (0.00%)	1 / 76 (1.32%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	1 / 72 (1.39%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Device Dislocation			

subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Withdrawal Syndrome			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Post-Traumatic Stress Disorder			

subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Adolescents: SP0173 Formulation 1	Adolescents: SP0173 Formulation 2	Adolescents: SP0173 Formulation 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 79 (89.87%)	64 / 71 (90.14%)	67 / 77 (87.01%)
Nervous system disorders			
Headache			
subjects affected / exposed	23 / 79 (29.11%)	15 / 71 (21.13%)	19 / 77 (24.68%)
occurrences (all)	25	15	21
General disorders and administration site conditions			
Change In Limb Circumference			
subjects affected / exposed	45 / 79 (56.96%)	41 / 71 (57.75%)	49 / 77 (63.64%)
occurrences (all)	45	41	49
Injection Site Erythema			
subjects affected / exposed	9 / 79 (11.39%)	4 / 71 (5.63%)	10 / 77 (12.99%)
occurrences (all)	9	4	10
Injection Site Pain			
subjects affected / exposed	59 / 79 (74.68%)	51 / 71 (71.83%)	50 / 77 (64.94%)
occurrences (all)	59	51	50
Injection Site Swelling			

subjects affected / exposed	7 / 79 (8.86%)	4 / 71 (5.63%)	8 / 77 (10.39%)
occurrences (all)	7	4	8
Malaise			
subjects affected / exposed	14 / 79 (17.72%)	17 / 71 (23.94%)	14 / 77 (18.18%)
occurrences (all)	14	17	14
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	3 / 79 (3.80%)	3 / 71 (4.23%)	4 / 77 (5.19%)
occurrences (all)	3	3	4
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 79 (1.27%)	4 / 71 (5.63%)	4 / 77 (5.19%)
occurrences (all)	1	4	4
Oropharyngeal Pain			
subjects affected / exposed	2 / 79 (2.53%)	5 / 71 (7.04%)	2 / 77 (2.60%)
occurrences (all)	2	5	2
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	42 / 79 (53.16%)	35 / 71 (49.30%)	38 / 77 (49.35%)
occurrences (all)	42	35	38
Infections and infestations			
Pharyngitis			
subjects affected / exposed	3 / 79 (3.80%)	7 / 71 (9.86%)	3 / 77 (3.90%)
occurrences (all)	3	10	3
Pharyngitis Streptococcal			
subjects affected / exposed	5 / 79 (6.33%)	4 / 71 (5.63%)	5 / 77 (6.49%)
occurrences (all)	5	4	7
Viral Pharyngitis			
subjects affected / exposed	3 / 79 (3.80%)	4 / 71 (5.63%)	2 / 77 (2.60%)
occurrences (all)	3	4	3

Non-serious adverse events	Adolescents: SP0173 Formulation 4	Adolescents: Adacel®	Adolescents: Boostrix®
Total subjects affected by non-serious adverse events			
subjects affected / exposed	68 / 77 (88.31%)	71 / 75 (94.67%)	66 / 75 (88.00%)
Nervous system disorders			

Headache			
subjects affected / exposed	25 / 77 (32.47%)	22 / 75 (29.33%)	29 / 75 (38.67%)
occurrences (all)	26	22	30
General disorders and administration site conditions			
Change In Limb Circumference			
subjects affected / exposed	46 / 77 (59.74%)	48 / 75 (64.00%)	33 / 75 (44.00%)
occurrences (all)	46	48	33
Injection Site Erythema			
subjects affected / exposed	1 / 77 (1.30%)	4 / 75 (5.33%)	2 / 75 (2.67%)
occurrences (all)	1	4	2
Injection Site Pain			
subjects affected / exposed	49 / 77 (63.64%)	59 / 75 (78.67%)	48 / 75 (64.00%)
occurrences (all)	49	59	48
Injection Site Swelling			
subjects affected / exposed	0 / 77 (0.00%)	1 / 75 (1.33%)	4 / 75 (5.33%)
occurrences (all)	0	1	4
Malaise			
subjects affected / exposed	18 / 77 (23.38%)	12 / 75 (16.00%)	17 / 75 (22.67%)
occurrences (all)	18	12	17
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 77 (1.30%)	3 / 75 (4.00%)	1 / 75 (1.33%)
occurrences (all)	1	3	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 77 (3.90%)	2 / 75 (2.67%)	0 / 75 (0.00%)
occurrences (all)	3	3	0
Oropharyngeal Pain			
subjects affected / exposed	2 / 77 (2.60%)	4 / 75 (5.33%)	0 / 75 (0.00%)
occurrences (all)	2	5	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	42 / 77 (54.55%)	52 / 75 (69.33%)	38 / 75 (50.67%)
occurrences (all)	42	52	38
Infections and infestations			

Pharyngitis			
subjects affected / exposed	5 / 77 (6.49%)	3 / 75 (4.00%)	2 / 75 (2.67%)
occurrences (all)	5	5	2
Pharyngitis Streptococcal			
subjects affected / exposed	5 / 77 (6.49%)	2 / 75 (2.67%)	4 / 75 (5.33%)
occurrences (all)	5	2	5
Viral Pharyngitis			
subjects affected / exposed	2 / 77 (2.60%)	0 / 75 (0.00%)	1 / 75 (1.33%)
occurrences (all)	2	0	1

Non-serious adverse events	Adults: SP0173 Formulation 1	Adults: SP0173 Formulation 2	Adults: SP0173 Formulation 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 76 (68.42%)	53 / 73 (72.60%)	67 / 76 (88.16%)
Nervous system disorders			
Headache			
subjects affected / exposed	16 / 76 (21.05%)	11 / 73 (15.07%)	19 / 76 (25.00%)
occurrences (all)	16	11	19
General disorders and administration site conditions			
Change In Limb Circumference			
subjects affected / exposed	28 / 76 (36.84%)	37 / 73 (50.68%)	41 / 76 (53.95%)
occurrences (all)	28	37	41
Injection Site Erythema			
subjects affected / exposed	2 / 76 (2.63%)	1 / 73 (1.37%)	2 / 76 (2.63%)
occurrences (all)	2	1	2
Injection Site Pain			
subjects affected / exposed	38 / 76 (50.00%)	34 / 73 (46.58%)	49 / 76 (64.47%)
occurrences (all)	38	34	49
Injection Site Swelling			
subjects affected / exposed	1 / 76 (1.32%)	3 / 73 (4.11%)	4 / 76 (5.26%)
occurrences (all)	1	3	4
Malaise			
subjects affected / exposed	18 / 76 (23.68%)	9 / 73 (12.33%)	16 / 76 (21.05%)
occurrences (all)	18	9	16
Gastrointestinal disorders			
Abdominal Pain			

subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 76 (0.00%)	1 / 73 (1.37%)	2 / 76 (2.63%)
occurrences (all)	0	1	2
Oropharyngeal Pain			
subjects affected / exposed	1 / 76 (1.32%)	2 / 73 (2.74%)	4 / 76 (5.26%)
occurrences (all)	1	2	5
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	32 / 76 (42.11%)	29 / 73 (39.73%)	35 / 76 (46.05%)
occurrences (all)	32	29	35
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 76 (0.00%)	1 / 73 (1.37%)	1 / 76 (1.32%)
occurrences (all)	0	1	1
Viral Pharyngitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 73 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Adults: SP0173 Formulation 4	Adults: Adacel®	Adults: Boostrix®
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 76 (71.05%)	62 / 76 (81.58%)	50 / 72 (69.44%)
Nervous system disorders			
Headache			
subjects affected / exposed	19 / 76 (25.00%)	19 / 76 (25.00%)	19 / 72 (26.39%)
occurrences (all)	19	19	21
General disorders and administration site conditions			
Change In Limb Circumference			
subjects affected / exposed	37 / 76 (48.68%)	35 / 76 (46.05%)	31 / 72 (43.06%)
occurrences (all)	37	35	31
Injection Site Erythema			

subjects affected / exposed	0 / 76 (0.00%)	5 / 76 (6.58%)	2 / 72 (2.78%)
occurrences (all)	0	5	2
Injection Site Pain			
subjects affected / exposed	42 / 76 (55.26%)	49 / 76 (64.47%)	35 / 72 (48.61%)
occurrences (all)	42	49	35
Injection Site Swelling			
subjects affected / exposed	1 / 76 (1.32%)	3 / 76 (3.95%)	1 / 72 (1.39%)
occurrences (all)	1	3	1
Malaise			
subjects affected / exposed	19 / 76 (25.00%)	23 / 76 (30.26%)	15 / 72 (20.83%)
occurrences (all)	19	23	15
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 76 (1.32%)	2 / 76 (2.63%)	1 / 72 (1.39%)
occurrences (all)	1	2	1
Oropharyngeal Pain			
subjects affected / exposed	1 / 76 (1.32%)	0 / 76 (0.00%)	2 / 72 (2.78%)
occurrences (all)	1	0	2
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	36 / 76 (47.37%)	39 / 76 (51.32%)	28 / 72 (38.89%)
occurrences (all)	36	39	28
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 76 (0.00%)	1 / 76 (1.32%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Viral Pharyngitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 76 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Older Adults: SP0173 Formulation 1	Older Adults: SP0173 Formulation 2	Older Adults: SP0173 Formulation 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 77 (68.83%)	60 / 73 (82.19%)	58 / 78 (74.36%)
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 77 (7.79%)	10 / 73 (13.70%)	20 / 78 (25.64%)
occurrences (all)	6	10	20
General disorders and administration site conditions			
Change In Limb Circumference			
subjects affected / exposed	38 / 77 (49.35%)	43 / 73 (58.90%)	36 / 78 (46.15%)
occurrences (all)	38	43	36
Injection Site Erythema			
subjects affected / exposed	0 / 77 (0.00%)	1 / 73 (1.37%)	2 / 78 (2.56%)
occurrences (all)	0	1	2
Injection Site Pain			
subjects affected / exposed	22 / 77 (28.57%)	34 / 73 (46.58%)	34 / 78 (43.59%)
occurrences (all)	22	34	34
Injection Site Swelling			
subjects affected / exposed	1 / 77 (1.30%)	6 / 73 (8.22%)	6 / 78 (7.69%)
occurrences (all)	1	6	6
Malaise			
subjects affected / exposed	6 / 77 (7.79%)	12 / 73 (16.44%)	14 / 78 (17.95%)
occurrences (all)	6	12	14
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Oropharyngeal Pain			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			

Myalgia			
subjects affected / exposed	12 / 77 (15.58%)	21 / 73 (28.77%)	31 / 78 (39.74%)
occurrences (all)	12	21	31
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Viral Pharyngitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Older Adults: SP0173 Formulation 4	Older Adults: Adacel®	Older Adults: Boostrix®
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 72 (73.61%)	49 / 76 (64.47%)	56 / 78 (71.79%)
Nervous system disorders			
Headache			
subjects affected / exposed	12 / 72 (16.67%)	11 / 76 (14.47%)	14 / 78 (17.95%)
occurrences (all)	12	11	15
General disorders and administration site conditions			
Change In Limb Circumference			
subjects affected / exposed	38 / 72 (52.78%)	32 / 76 (42.11%)	40 / 78 (51.28%)
occurrences (all)	38	32	40
Injection Site Erythema			
subjects affected / exposed	2 / 72 (2.78%)	3 / 76 (3.95%)	1 / 78 (1.28%)
occurrences (all)	2	3	1
Injection Site Pain			
subjects affected / exposed	34 / 72 (47.22%)	28 / 76 (36.84%)	25 / 78 (32.05%)
occurrences (all)	34	28	25
Injection Site Swelling			
subjects affected / exposed	2 / 72 (2.78%)	1 / 76 (1.32%)	2 / 78 (2.56%)
occurrences (all)	2	1	2
Malaise			

subjects affected / exposed	9 / 72 (12.50%)	8 / 76 (10.53%)	6 / 78 (7.69%)
occurrences (all)	9	8	6
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 72 (1.39%)	0 / 76 (0.00%)	2 / 78 (2.56%)
occurrences (all)	1	0	2
Oropharyngeal Pain			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	23 / 72 (31.94%)	23 / 76 (30.26%)	18 / 78 (23.08%)
occurrences (all)	23	23	18
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Viral Pharyngitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 76 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 September 2015	Following amendments were made: - To add an unscheduled visit for subjects who presented a Grade 3 solicited adverse event. - To include a 6-month follow-up after vaccination.
13 May 2016	Amendment 2.0 was to adjust the number of sites were the trial was going to be conducted. - To clarify that sites should follow state law with regard to the age of majority for consent. - The definition of Category 2 concomitant medication was also revised such that allergy hyposensitization therapy and topical analgesics were not to be recorded as Category 2.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported