

**Clinical trial results:
Immunogenicity and Safety of the SP059 Given Subcutaneously as a
Three-Dose Primary and Booster Vaccination in Infants in Japan
Summary**

EudraCT number	2015-005187-42
Trial protocol	Outside EU/EEA
Global end of trial date	08 November 2011

Results information

Result version number	v1 (current)
This version publication date	16 April 2016
First version publication date	16 April 2016

Trial information**Trial identification**

Sponsor protocol code	IPV35_EFC12403
-----------------------	----------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01389687
WHO universal trial number (UTN)	U1111-1120-1735

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur K.K.
Sponsor organisation address	3-20-2, Nishi Shinjuku, Shinjuku-ku, Tokyo, Japan, 163-1488
Public contact	Head of Local Medical Operation, Sanofi Aventis K.K., Toshiaki.Sato@sanofi.com
Scientific contact	Head of Local Medical Operation, Sanofi Aventis K.K., Toshiaki.Sato@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	08 November 2011
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 November 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1) To assess that the seroprotection rates against polio types 1, 2 and 3 are over 90% approximately one month following the three dose primary vaccination series with inactivated polio vaccine (IPV).

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were randomized and vaccinated in the study. 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 allergic reactions.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 July 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Japan: 74
Worldwide total number of subjects	74
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)	74
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study subjects were enrolled from 01 July 2011 to 08 November 2011 (primary series) and to 30 June 2012 (booster series) at 2 clinic centers in Japan.

Pre-assignment

Screening details:

A total of 74 subjects who met all the inclusion and none of the exclusion criteria were enrolled and vaccinated in the primary series study; 73 subjects in the booster series.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable

Arms

Arm title	SP059 (Inactivated Poliovirus Vaccine; IPV)
------------------	---

Arm description:

Subjects received three doses of Inactivated poliovirus vaccine (IPV) administered 3-8 weeks (21-56 days) apart as a three-dose primary vaccination starting at 3-68 (recommended 3-8 months) of age and followed by a single dose of IPV as a booster vaccination 6-18 months after completion of the three-dose primary vaccination.

Arm type	Experimental
Investigational medicinal product name	SP059 (Inactivated Poliovirus vaccine types 1, 2, and 3)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous into the internal area of upper arm, 1 injection each at Day 0, 56, and 112 as primary vaccination series and a single booster dose 6-18 months post-dose 3.

Number of subjects in period 1	SP059 (Inactivated Poliovirus Vaccine; IPV)
Started	74
Completed	74

Baseline characteristics

Reporting groups

Reporting group title	SP059 (Inactivated Poliovirus Vaccine; IPV)
-----------------------	---

Reporting group description:

Subjects received three doses of Inactivated poliovirus vaccine (IPV) administered 3-8 weeks (21-56 days) apart as a three-dose primary vaccination starting at 3-68 (recommended 3-8 months) of age and followed by a single dose of IPV as a booster vaccination 6-18 months after completion of the three-dose primary vaccination.

Reporting group values	SP059 (Inactivated Poliovirus Vaccine; IPV)	Total	
Number of subjects	74	74	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	74	74	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: months			
arithmetic mean	5.1		
standard deviation	± 1.1	-	
Gender categorical			
Units: Subjects			
Female	35	35	
Male	39	39	

Subject analysis sets

Subject analysis set title	SP059 (Inactivated Poliovirus vaccine; IPV; Booster dose)
----------------------------	---

Subject analysis set type	Full analysis
---------------------------	---------------

Subject analysis set description:

All subjects received a single dose of IPV as a booster vaccination 6-18 months after completion of the three-dose primary vaccination.

Reporting group values	SP059 (Inactivated Poliovirus vaccine; IPV; Booster dose)		
Number of subjects	73		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		

Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	73		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: months			
arithmetic mean	14.9		
standard deviation	± 1.4		
Gender categorical			
Units: Subjects			
Female	35		
Male	38		

End points

End points reporting groups

Reporting group title	SP059 (Inactivated Poliovirus Vaccine; IPV)
Reporting group description: Subjects received three doses of Inactivated poliovirus vaccine (IPV) administered 3-8 weeks (21-56 days) apart as a three-dose primary vaccination starting at 3-68 (recommended 3-8 months) of age and followed by a single dose of IPV as a booster vaccination 6-18 months after completion of the three-dose primary vaccination.	
Subject analysis set title	SP059 (Inactivated Poliovirus vaccine; IPV; Booster dose)
Subject analysis set type	Full analysis
Subject analysis set description: All subjects received a single dose of IPV as a booster vaccination 6-18 months after completion of the three-dose primary vaccination.	

Primary: Percentage of Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Before and Following A Three-Dose Primary Series Vaccination of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Percentage of Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Before and Following A Three-Dose Primary Series Vaccination of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) ^[1]
End point description: Anti-Poliovirus types 1, 2, and 3 titers were measured by neutralization assay. Seroprotection was defined as Anti-Poliovirus 1, 2, and 3 antibody titers ≥ 8 (1/dil).	
End point type	Primary
End point timeframe: Pre-Primary and Post-Primary 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	SP059 (Inactivated Poliovirus Vaccine; IPV)			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: Percentage of subjects number (not applicable)				
Anti-Poliovirus 1; Pre-Primary	2.7			
Anti-Poliovirus 1; Post-Primary	100			
Anti-Poliovirus 2; Pre-Primary	18.9			
Anti-Poliovirus 2; Post-Primary	100			
Anti-Poliovirus 3; Pre-Primary	0			
Anti-Poliovirus 3; Post-Primary	100			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers of Anti-polio 1, 2, and 3 Antibodies Before and Following A Three-Dose Primary Series Vaccination of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Geometric Mean Titers of Anti-polio 1, 2, and 3 Antibodies Before and Following A Three-Dose Primary Series Vaccination of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) ^[2]
-----------------	---

End point description:

Anti-Poliovirus types 1, 2, and 3 titers were measured by neutralization assay.

End point type	Primary
----------------	---------

End point timeframe:

Pre-Primary and Post-Primary Vaccination

Notes:

[2] - 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	SP059 (Inactivated Poliovirus Vaccine; IPV)			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; Pre-Primary	2.2 (2.1 to 2.4)			
Anti-Poliovirus 1; Post-Primary	291.9 (242.1 to 351.8)			
Anti-Poliovirus 2; Pre-Primary	3.3 (2.5 to 4.3)			
Anti-Poliovirus 2; Post-Primary	559.6 (463.5 to 675.7)			
Anti-Poliovirus 3; Pre-Primary	2.1 (2 to 2.2)			
Anti-Poliovirus 3; Post-Primary	432.6 (348.4 to 537.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titer Ratios of Anti-polio 1, 2, and 3 Antibodies Before and Following A Three-Dose Primary Series Vaccination of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Geometric Mean Titer Ratios of Anti-polio 1, 2, and 3 Antibodies Before and Following A Three-Dose Primary Series Vaccination of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) ^[3]
-----------------	---

End point description:

Anti-Poliovirus types 1, 2, and 3 titers were measured by neutralization assay.

End point type	Primary
----------------	---------

End point timeframe:

Post-Primary/Pre-Primary 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	SP059 (Inactivated Poliovirus Vaccine; IPV)			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: Titer ratio (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; Post-Primary	130.4 (108.1 to 157.3)			
Anti-Poliovirus 2; Post-Primary	171.9 (130.7 to 226)			
Anti-Poliovirus 3; Post-Primary	208.3 (166 to 261.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Solicited Injection-site and Systemic Reactions Following A Three-Dose Primary Series Vaccination of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Percentage of Subjects with Solicited Injection-site and Systemic Reactions Following A Three-Dose Primary Series Vaccination of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) ^[4]
-----------------	---

End point description:

Solicited injection site reactions (3 to 23 months): Tenderness, Erythema, and Swelling; (2 to 11 years): Pain, Erythema, and Swelling. Solicited systemic reactions (3 to 23 months): Fever, Vomiting, Crying abnormal, Drowsiness, Appetite lost, Irritability and (2 to 11 years): Fever, Headache, Malaise, and Myalgia.

Grade 3 injection site reactions: Tenderness (3 to 23 months), Cries when injected limb is moved or the movement of the injected limb is reduced; Pain (2 to 11 years), Incapacitating, unable to perform usual activities; Erythema and Swelling, ≥ 50 mm. Grade 3 systemic reactions (3 to 23 months): Fever, $\geq 39.0^{\circ}\text{C}$; Vomiting, ≥ 6 episodes per 24 hours or requires parenteral hydration; Crying abnormal, > 3 hours; Drowsiness, Sleeping most of the time or difficult to wake; Appetite lost, Refuses ≥ 3 feeds/meals or refuses most feeds/meals; Irritability, Inconsolable and (2 to 11 years): Fever, $\geq 39.0^{\circ}\text{C}$; Headache, Malaise, and Myalgia, Significant, prevents daily activity.

End point type	Primary
----------------	---------

End point timeframe:

Day 0 up to Day 7 post-any dose primary series

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	SP059 (Inactivated Poliovirus Vaccine; IPV)			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: Percentage of subjects				
number (not applicable)				
Any Injection site Tenderness; Post-dose 1	2.7			
Grade 3 Injection site Tenderness; Post-dose 1	0			
Any Injection site Tenderness; Post-dose 2	1.4			
Grade 3 Injection site Tenderness; Post-dose 2	0			
Any Injection site Tenderness; Post-dose 3	5.4			
Grade 3 Injection site Tenderness; Post-dose 3	0			
Any Injection site Tenderness; Primary series	8.1			
Grade 3 Injection site Tenderness; Primary series	0			
Any Injection site Erythema; Post-dose 1	51.4			
Grade 3 Injection site Erythema; Post-dose 1	0			
Any Injection site Erythema; Post-dose 2	51.4			
Grade 3 Injection site Erythema; Post-dose 2	0			
Any Injection site Erythema; Post-dose 3	47.3			
Grade 3 Injection site Erythema; Post-dose 3	0			
Any Injection site Erythema; Primary series	66.2			
Grade 3 Injection site Erythema; Primary series	0			
Any Injection site Swelling; Post-dose 1	20.3			
Grade 3 Injection site Swelling; Post-dose 1	0			
Any Injection site Swelling; Post-dose 2	27			
Grade 3 Injection site Swelling; Post-dose 2	0			
Any Injection site Swelling; Post-dose 3	21.6			
Grade 3 Injection site Swelling; Post-dose 3	0			
Any Injection site Swelling; Primary series	37.8			
Grade 3 Injection site Swelling; Primary series	0			
Any Fever; Post-dose 1	5.4			
Grade 3 Fever; Post-dose 1	0			
Any Fever; Post-dose 2	5.4			
Grade 3 Fever; Post-dose 2	0			
Any Fever; Post-dose 3	4.1			
Grade 3 Fever; Post-dose 3	2.7			
Any Fever; Primary series	14.9			

Grade 3 Fever; Primary series	2.7			
Any Vomiting; Post-dose 1	8.1			
Grade 3 Vomiting; Post-dose 1	0			
Any Vomiting; Post-dose 2	10.8			
Grade 3 Vomiting; Post-dose 2	0			
Any Vomiting; Post-dose 3	5.4			
Grade 3 Vomiting; Post-dose 3	0			
Any Vomiting; Primary series	18.9			
Grade 3 Vomiting; Primary series	0			
Any Crying abnormal; Post-dose 1	6.8			
Grade 3 Crying abnormal; Post-dose 1	0			
Any Crying abnormal; Post-dose 2	10.8			
Grade 3 Crying abnormal; Post-dose 2	0			
Any Crying abnormal; Post-dose 3	5.4			
Grade 3 Crying abnormal; Post-dose 3	0			
Any Crying abnormal; Primary series	17.6			
Grade 3 Crying abnormal; Primary series	0			
Any Drowsiness; Post-dose 1	12.2			
Grade 3 Drowsiness; Post-dose 1	0			
Any Drowsiness; Post-dose 2	17.6			
Grade 3 Drowsiness; Post-dose 2	0			
Any Drowsiness; Post-dose 3	12.2			
Grade 3 Drowsiness; Post-dose 3	0			
Any Drowsiness; Primary series	29.7			
Grade 3 Drowsiness; Primary series	0			
Any Appetite lost; Post-dose 1	6.8			
Grade 3 Appetite lost; Post-dose 1	0			
Any Appetite lost; Post-dose 2	6.8			
Grade 3 Appetite lost; Post-dose 2	0			
Any Appetite lost; Post-dose 3	1.4			
Grade 3 Appetite lost; Post-dose 3	0			
Any Appetite lost; Primary series	12.2			
Grade 3 Appetite lost; Primary series	0			
Any Irritability; Post-dose 1	17.6			
Grade 3 Irritability; Post-dose 1	1.4			
Any Irritability; Post-dose 2	16.2			
Grade 3 Irritability; Post-dose 2	0			
Any Irritability; Post-dose 3	14.9			
Grade 3 Irritability; Post-dose 3	0			
Any Irritability; Primary series	32.4			
Grade 3 Irritability; Primary series	1.4			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Before and Following A Booster Dose of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Percentage of Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Before and Following A Booster Dose of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) ^[5]
End point description: Anti-Poliovirus types 1, 2, and 3 were measured by neutralization assay. Seroprotection was defined as Anti-Poliovirus 1, 2, and 3 antibody titers ≥ 8 (1/dil).	
End point type	Primary

End point timeframe:
Pre-Booster and Post-Booster 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	SP059 (Inactivated Poliovirus vaccine; IPV; Booster dose)			
Subject group type	Subject analysis set			
Number of subjects analysed	73			
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1; Pre-Booster	100			
Anti-Poliovirus 1; Post-Booster	100			
Anti-Poliovirus 2; Pre-Booster	100			
Anti-Poliovirus 2; Post-Booster	100			
Anti-Poliovirus 3; Pre-Booster	97.3			
Anti-Poliovirus 3; Post-Booster	100			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers of Anti-polio 1, 2, and 3 Antibodies Before and Following A Booster Dose of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Geometric Mean Titers of Anti-polio 1, 2, and 3 Antibodies Before and Following A Booster Dose of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) ^[6]
End point description: Anti-Poliovirus types 1, 2, and 3 were measured by neutralization assay.	
End point type	Primary

End point timeframe:
Pre-Booster and Post-Booster Vaccination

Notes:

[6] - 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	SP059 (Inactivated Poliovirus vaccine; IPV; Booster dose)			
Subject group type	Subject analysis set			
Number of subjects analysed	73			
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; Pre-Booster	281.5 (224 to 353.7)			
Anti-Poliovirus 1; Post-Booster	3906.1 (3217.1 to 4742.6)			
Anti-Poliovirus 2; Pre-Booster	519.3 (429.7 to 627.6)			
Anti-Poliovirus 2; Post-Booster	3742.7 (3046.8 to 4597.6)			
Anti-Poliovirus 3; Pre-Booster	98.6 (72.2 to 134.6)			
Anti-Poliovirus 3; Post-Booster	6775.1 (5292 to 8673.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titer Ratios of Anti-polio 1, 2, and 3 Antibodies Following A Booster Dose of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Geometric Mean Titer Ratios of Anti-polio 1, 2, and 3 Antibodies Following A Booster Dose of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) ^[7]
-----------------	---

End point description:

Anti-Poliovirus types 1, 2, and 3 were measured by neutralization assay.

End point type	Primary
----------------	---------

End point timeframe:

Post-Booster/Pre-Booster Vaccination

Notes:

[7] - 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	SP059 (Inactivated Poliovirus vaccine; IPV; Booster dose)			
Subject group type	Subject analysis set			
Number of subjects analysed	73			
Units: Titer ratios (1/dil)				
geometric mean (confidence interval 95%)				

Anti-Poliovirus 1; Post-Booster	13.9 (10.5 to 18.3)			
Anti-Poliovirus 2; Post-Booster	7.2 (5.6 to 9.3)			
Anti-Poliovirus 3; Post-Booster	68.7 (47.8 to 98.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Solicited Injection-site and Systemic Reactions Following A Booster Dose of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Percentage of Subjects with Solicited Injection-site and Systemic Reactions Following A Booster Dose of Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) ^[8]
-----------------	--

End point description:

Solicited injection site reactions (3 to 23 months): Tenderness, Erythema, and Swelling; (2 to 11 years): Pain, Erythema, and Swelling. Solicited systemic reactions (3 to 23 months): Fever, Vomiting, Crying abnormal, Drowsiness, Appetite lost, Irritability and (2 to 11 years): Fever, Headache, Malaise, and Myalgia.

Grade 3 injection site reactions: Tenderness (3 to 23 months), Cries when injected limb is moved or the movement of the injected limb is reduced; Pain (2 to 11 years), Incapacitating, unable to perform usual activities; Erythema and Swelling, ≥ 50 mm. Grade 3 systemic reactions (3 to 23 months): Fever, $\geq 39.0^{\circ}\text{C}$; Vomiting, ≥ 6 episodes per 24 hours or requires parenteral hydration; Crying abnormal, > 3 hours; Drowsiness, Sleeping most of the time or difficult to wake; Appetite lost, Refuses ≥ 3 feeds/meals or refuses most feeds/meals; Irritability, Inconsolable and (2 to 11 years): Fever, $\geq 39.0^{\circ}\text{C}$; Headache, Malaise, and Myalgia, Significant, prevents daily activity.

End point type	Primary
----------------	---------

End point timeframe:

Day 0 up to Day 7 post-booster vaccination

Notes:

[8] - 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	SP059 (Inactivated Poliovirus vaccine; IPV; Booster dose)			
Subject group type	Subject analysis set			
Number of subjects analysed	73			
Units: Percentage of subjects number (not applicable)				
Any Injection site Tenderness	13.7			
Grade 3 Injection site Tenderness	0			
Any Injection site Erythema	52.1			
Grade 3 Injection site Erythema	0			
Any Injection site Swelling	27.4			
Grade 3 Injection site Swelling	0			
Any Fever	21.9			
Grade 3 Fever	5.5			
Any Vomiting	6.8			

Grade 3 Vomiting	0			
Any Crying abnormal	11			
Grade 3 Crying abnormal	0			
Any Drowsiness	17.8			
Grade 3 Drowsiness	0			
Any Appetite lost	17.8			
Grade 3 Appetite lost	0			
Any Irritability	21.9			
Grade 3 Irritability	1.4			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event data were collected from Day 0 of primary series up to Day 7 post-booster vaccination.

Assessment type	Non-systematic
-----------------	----------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	14.1
--------------------	------

Reporting groups

Reporting group title	SP059 (Inactivated Poliovirus Vaccine; IPV)
-----------------------	---

Reporting group description:

Subjects received three doses of Inactivated poliovirus vaccine (IPV) administered 3-8 weeks (21-56 days) apart as a three-dose primary vaccination starting at 3-68 (recommended 3-8 months) of age and followed by a single dose of IPV as a booster vaccination 6-18 months after completion of the three-dose primary vaccination.

Reporting group title	SP059 (Inactivated Poliovirus Vaccine; IPV; Booster dose)
-----------------------	---

Reporting group description:

All subjects received a single dose of IPV as a booster vaccination 6-18 months after completion of the three-dose primary vaccination.

Serious adverse events	SP059 (Inactivated Poliovirus Vaccine; IPV)	SP059 (Inactivated Poliovirus Vaccine; IPV; Booster dose)	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 74 (6.76%)	9 / 73 (12.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Tremor			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Afebrile convulsion			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile convulsion			
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Asthmatic bronchitis			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute bronchitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	SP059 (Inactivated Poliovirus Vaccine; IPV)	SP059 (Inactivated Poliovirus Vaccine; IPV; Booster dose)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 74 (71.62%)	41 / 73 (56.16%)	
Nervous system disorders			
Any Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 74 (29.73%)	13 / 73 (17.81%)	
occurrences (all)	22	13	
General disorders and administration site conditions			

Any Injection site Tenderness alternative assessment type: Systematic subjects affected / exposed occurrences (all)	6 / 74 (8.11%) 6	10 / 73 (13.70%) 10	
Any Injection site Erythema alternative assessment type: Systematic subjects affected / exposed occurrences (all)	49 / 74 (66.22%) 49	38 / 73 (52.05%) 38	
Any Injection site Swelling alternative assessment type: Systematic subjects affected / exposed occurrences (all)	28 / 74 (37.84%) 28	20 / 73 (27.40%) 20	
Any Fever alternative assessment type: Systematic subjects affected / exposed occurrences (all)	11 / 74 (14.86%) 11	16 / 73 (21.92%) 16	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	7 / 74 (9.46%) 7	3 / 73 (4.11%) 3	
Any Vomiting alternative assessment type: Systematic subjects affected / exposed occurrences (all)	14 / 74 (18.92%) 14	5 / 73 (6.85%) 5	
Respiratory, thoracic and mediastinal disorders Upper respiratory tract inflammation subjects affected / exposed occurrences (all)	16 / 74 (21.62%) 16	11 / 73 (15.07%) 11	
Skin and subcutaneous tissue disorders Dermatitis diaper subjects affected / exposed occurrences (all)	5 / 74 (6.76%) 5	0 / 73 (0.00%) 0	
Eczema subjects affected / exposed occurrences (all)	4 / 74 (5.41%) 4	2 / 73 (2.74%) 2	
Psychiatric disorders			

Any Crying abnormal alternative assessment type: Systematic subjects affected / exposed occurrences (all)	13 / 74 (17.57%) 13	8 / 73 (10.96%) 8	
Any Irritability alternative assessment type: Systematic subjects affected / exposed occurrences (all)	24 / 74 (32.43%) 24	16 / 73 (21.92%) 16	
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	10 / 74 (13.51%) 10	6 / 73 (8.22%) 6	
Bronchitis subjects affected / exposed occurrences (all)	5 / 74 (6.76%) 5	5 / 73 (6.85%) 5	
Gastroenteritis subjects affected / exposed occurrences (all)	4 / 74 (5.41%) 4	5 / 73 (6.85%) 5	
Hand-foot-and-mouth disease subjects affected / exposed occurrences (all)	4 / 74 (5.41%) 4	0 / 73 (0.00%) 0	
Metabolism and nutrition disorders Any Appetite lost alternative assessment type: Systematic subjects affected / exposed occurrences (all)	9 / 74 (12.16%) 9	13 / 73 (17.81%) 13	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 June 2011	Added the secondary endpoint for the evaluation of immunogenicity.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported