Clinical trial results:
A Phase I/II, randomized, controlled, observer-blind, multi-center study to assess the reactogenicity, safety and immunogenicity of three GlaxoSmithKline (GSK) Biologicals' investigational supra-seasonal universal influenza vaccines (SUIVs) (unadjuvanted or adjuvanted with AS03 or AS01) administered as a 1 or 2-dose priming schedule followed by a booster dose 12 months post-primary vaccination in 18 to 39 year-old healthy subjects

Summary

EudraCT number	2017-001584-20
Trial protocol	BE
Global end of trial date	26 March 2020

Results information

Result version number	v1
This version publication date	01 April 2021
First version publication date	01 April 2021

Trial information

Trial identification

Sponsor protocol code	207543

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03275389
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 March 2020
Global end of trial reached?	Yes
Global end of trial date	26 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the reactogenicity and safety of each vaccine dose throughout the entire study period, in all study groups. To describe the anti-H1 stalk humoral immune response 28 days after each priming dose (1 or 2 dose(s)) in all study groups.

Protection of trial subjects:

The subjects were observed closely for at least 60 minutes (Phase I subjects) or 30 minutes (Phase II subjects) following the administration of the vaccines/products, with appropriate medical treatment readily available in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 September 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 101
Country: Number of subjects enrolled	United States: 369
Worldwide total number of subjects	470
EEA total number of subjects	101

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	470
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

470 subjects were enrolled and randomized in the study, however, while 2 subjects were allocated subjects numbers, they did not receive any vaccine dose.

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, Monitor, Assessor

Blinding implementation details:

The site staff worked in an observer-blind manner. As the vaccines appearance and preparation were different, two teams of study personnel were set up:
- A team of unblinded personnel (responsible for the reception, preparation and administration of the vaccines).
- A team of blinded personnel (responsible for the clinical safety evaluation of the subjects).

Arms

Are arms mutually exclusive?	Yes
Arm title	D-SUIV Adjuvanted Group 1

Arm description:

Subjects received one dose of D-SUIV cH8/1N1+AS03 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH8/1N1+AS03 Placebo D-SUIV cH5/1N1+AS03
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH8/1N1+AS03) 1 dose at Day 57 (Placebo); 1 dose at Month 14 (D-SUIV cH5/1N1+AS03)

Arm title	D-SUIV Adjuvanted Group 2

Arm description:

Subjects received one dose of D-SUIV cH5/1N1+AS03 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH5/1N1+AS03 Placebo D-SUIV cH8/1N1+AS03
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH5/1N1+AS03);
1 dose at Day 57 (Placebo);
1 dose at Month 14 (D-SUIV cH8/1N1+AS03)

Arm title	D-SUIV Adjuvanted Group 3

Arm description:

Subjects received one dose of D-SUIV cH8/1N1+AS03 vaccine at Day 1, one dose D-SUIV cH5/1N1+AS03 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH8/1N1+AS03 D-SUIV cH5/1N1+AS03 D-SUIV cH11/1N1+AS03
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH8/1N1+AS03);
1 dose at Day 57 (D-SUIV cH5/1N1+AS03);
1 dose at Month 14 (D-SUIV cH11/1N1+AS03)

Arm title	D-SUIV Adjuvanted Group 4

Arm description:

Subjects received one dose of D-SUIV cH8/1N1+AS01 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH8/1N1+AS01 Placebo D-SUIV cH5/1N1+AS01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH8/1N1+AS01);
1 dose at Day 57 (Placebo);
1 dose at Month 14 (D-SUIV cH5/1N1+AS01)

Arm title	D-SUIV Adjuvanted Group 5

Arm description:

Subjects received one dose of D-SUIV cH5/1N1+AS01 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH5/1N1+AS01 Placebo D-SUIV cH8/1N1+AS01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH5/1N1+AS01);
1 dose at Day 57 (Placebo);
1 dose at Month 14 (D-SUIV cH8/1N1+AS01)

Arm title	D-SUIV Adjuvanted Group 6

Arm description:

Subjects received one dose of D-SUIV cH8/1N1+AS01 vaccine at Day 1, one dose of D-SUIV cH5/1N1+AS01 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH8/1N1+AS01 D-SUIV cH5/1N1+AS01 D-SUIV cH11/1N1+AS01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH8/1N1+AS01);
1 dose at Day 57 (D-SUIV cH5/1N1+AS01);
1 dose at Month 14 (D-SUIV cH11/1N1+AS01)

Arm title	D-SUIV Unadjuvanted Group 1

Arm description:

Subjects received one dose of D-SUIV cH8/1N1 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH8/1N1 Placebo D-SUIV cH5/1N1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH8/1N1);
1 dose at Day 57 (Placebo);
1 dose at Month 14 (D-SUIV cH5/1N1)

Arm title	D-SUIV Unadjuvanted Group 2

Arm description:

Subjects received one dose of D-SUIV cH5/1N1 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH5/1N1 Placebo D-SUIV cH8/1N1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH5/1N1);
1 dose at Day 57 (Placebo);
1 dose at Month 14 (D-SUIV cH8/1N1)

Arm title	D-SUIV Unadjuvanted Group 3

Arm description:

Subjects received one dose of D-SUIV cH8/1N1 vaccine at Day 1, one dose of D-SUIV cH5/1N1 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	D-SUIV cH8/1N1 D-SUIV cH5/1N1 D-SUIV cH11/1N1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (D-SUIV cH8/1N1);
1 dose at Day 57 (D-SUIV cH5/1N1);
1 dose at Month 14 (D-SUIV cH11/1N1)

Arm title	IIV4 Group

Arm description:

Subjects received one dose of Fluarix Quadrivalent (IIV4) vaccine at Day 1, one dose of Placebo at Day 57 and one dose of Fluarix Quadrivalent vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Arm type	Active comparator
Investigational medicinal product name	Fluarix Quadrivalent (IIV4); Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 1 (Fluarix Quadrivalent (IIV4))
1 dose at Day 57 (Placebo)
1 dose at Month 14 (Fluarix Quadrivalent)

Number of subjects in period 1[1]	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3
Started	45	46	47
Completed	34	30	24
Not completed	11	16	23
NOT WILLING TO PARTICIPATE THIS VISIT	-	-	1
Unknown	-	4	3
MIGRATED / MOVED FROM THE STUDY AREA	-	2	-
Lost to follow-up	10	10	19
SERIOUS ADVERSE EVENT AND/OR PIMD	-	-	-
CONSENT WITHDRAWAL NOT DUE TO ADV. EVENT	1	-	-

Number of subjects in period 1[1]	D-SUIV Adjuvanted Group 4	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6
Started	47	48	47
Completed	25	32	29
Not completed	22	16	18
NOT WILLING TO PARTICIPATE THIS VISIT	-	-	-

Unknown	2	2	2
MIGRATED / MOVED FROM THE STUDY AREA	3	-	-
Lost to follow-up	12	11	12
SERIOUS ADVERSE EVENT AND/OR PIMD	-	-	1
CONSENT WITHDRAWAL NOT DUE TO ADV. EVENT	5	3	3

Number of subjects in period 1[1]	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2	D-SUIV Unadjuvanted Group 3
Started	47	48	46
Completed	22	30	31
Not completed	25	18	15
NOT WILLING TO PARTICIPATE THIS VISIT	-	-	-
Unknown	-	-	1
MIGRATED / MOVED FROM THE STUDY AREA	1	-	-
Lost to follow-up	21	15	12
SERIOUS ADVERSE EVENT AND/OR PIMD	-	-	-
CONSENT WITHDRAWAL NOT DUE TO ADV. EVENT	3	3	2

Number of subjects in period 1[1]	IIV4 Group
Started	47
Completed	29
Not completed	18
NOT WILLING TO PARTICIPATE THIS VISIT	1
Unknown	-
MIGRATED / MOVED FROM THE STUDY AREA	-
Lost to follow-up	14
SERIOUS ADVERSE EVENT AND/OR PIMD	1
CONSENT WITHDRAWAL NOT DUE TO ADV. EVENT	2

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 470 subjects were enrolled and randomized in the study, however, while 2 subjects were allocated subjects numbers, they did not receive any vaccine dose.

Baseline characteristics

Reporting groups

Reporting group title	D-SUIV Adjuvanted Group 1
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1+AS03 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 2
Reporting group description:	
Subjects received one dose of D-SUIV cH5/1N1+AS03 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 3
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1+AS03 vaccine at Day 1, one dose D-SUIV cH5/1N1+AS03 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 4
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1+AS01 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 5
Reporting group description:	
Subjects received one dose of D-SUIV cH5/1N1+AS01 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 6
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1+AS01 vaccine at Day 1, one dose of D-SUIV cH5/1N1+AS01 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Unadjuvanted Group 1
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Unadjuvanted Group 2
Reporting group description:	
Subjects received one dose of D-SUIV cH5/1N1 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Unadjuvanted Group 3
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1 vaccine at Day 1, one dose of D-SUIV cH5/1N1 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	IIV4 Group
Reporting group description:	
Subjects received one dose of Fluarix Quadrivalent (IIV4) vaccine at Day 1, one dose of Placebo at Day 57 and one dose of Fluarix Quadrivalent vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	

Reporting group values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3
Number of subjects	45	46	47
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	45	46	47
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	29.0	29.3	28.6
standard deviation	± 6.6	± 5.7	± 6.0
Sex: Female, Male Units: Participants			
Female	26	27	28
Male	19	19	19
Race/Ethnicity, Customized Units: Subjects			
American indian or alaska native	0	0	0
Asian - central / south asian heritage	0	0	0
Asian - east asian heritage	0	1	0
Asian - south east asian heritage	0	1	0
Black or african american	11	9	10
Native hawaiian or other pacific islander	0	0	0
Other, Not specified	0	0	0
White - arabic / north african heritage	0	1	0
White - caucasian / european heritage	34	34	37

Reporting group values	D-SUIV Adjuvanted Group 4	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6
Number of subjects	47	48	47
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	47	48	47
From 65-84 years	0	0	0

85 years and over	0	0	0

Age continuous			
Units: years			
arithmetic mean	28.7	29.1	28.8
standard deviation	± 6.4	± 6.2	± 6.1
Sex: Female, Male			
Units: Participants			
Female	28	27	27
Male	19	21	20
Race/Ethnicity, Customized			
Units: Subjects			
American indian or alaska native	0	1	0
Asian - central / south asian heritage	0	0	0
Asian - east asian heritage	0	0	0
Asian - south east asian heritage	1	0	0
Black or african american	8	5	7
Native hawaiian or other pacific islander	0	0	0
Other, Not specified	2	2	1
White - arabic / north african heritage	0	0	1
White - caucasian / european heritage	36	40	38

Reporting group values	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2	D-SUIV Unadjuvanted Group 3
Number of subjects	47	48	46
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	47	48	46
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	29.6	28.5	28.8
standard deviation	± 5.8	± 5.9	± 5.9
Sex: Female, Male			
Units: Participants			
Female	27	26	25
Male	20	22	21

Race/Ethnicity, Customized Units: Subjects			
American indian or alaska native	0	0	0
Asian - central / south asian heritage	0	0	1
Asian - east asian heritage	0	0	0
Asian - south east asian heritage	0	0	0
Black or african american	10	13	6
Native hawaiian or other pacific islander	1	0	0
Other, Not specified	1	1	2
White - arabic / north african heritage	0	1	0
White - caucasian / european heritage	35	33	37

Reporting group values	IIV4 Group	Total	
Number of subjects	47	468	
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)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	47	468	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	29.3		
standard deviation	± 5.8	-	
Sex: Female, Male Units: Participants			
Female	27	268	
Male	20	200	
Race/Ethnicity, Customized Units: Subjects			
American indian or alaska native	0	1	
Asian - central / south asian heritage	0	1	
Asian - east asian heritage	0	1	
Asian - south east asian heritage	0	2	
Black or african american	9	88	
Native hawaiian or other pacific islander	0	1	
Other, Not specified	1	10	
White - arabic / north african heritage	2	5	
White - caucasian / european heritage	35	359	

End points

End points reporting groups

Reporting group title	D-SUIV Adjuvanted Group 1
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1+AS03 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 2
Reporting group description:	
Subjects received one dose of D-SUIV cH5/1N1+AS03 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 3
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1+AS03 vaccine at Day 1, one dose D-SUIV cH5/1N1+AS03 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 4
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1+AS01 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 5
Reporting group description:	
Subjects received one dose of D-SUIV cH5/1N1+AS01 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Adjuvanted Group 6
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1+AS01 vaccine at Day 1, one dose of D-SUIV cH5/1N1+AS01 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Unadjuvanted Group 1
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Unadjuvanted Group 2
Reporting group description:	
Subjects received one dose of D-SUIV cH5/1N1 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	D-SUIV Unadjuvanted Group 3
Reporting group description:	
Subjects received one dose of D-SUIV cH8/1N1 vaccine at Day 1, one dose of D-SUIV cH5/1N1 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	
Reporting group title	IIV4 Group
Reporting group description:	
Subjects received one dose of Fluarix Quadrivalent (IIV4) vaccine at Day 1, one dose of Placebo at Day 57 and one dose of Fluarix Quadrivalent vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.	

Primary: Number of subjects with solicited local adverse events (AEs) after first dose administration

End point title	Number of subjects with solicited local adverse events (AEs) after first dose administration[1]

End point description:

Assessed solicited local symptoms are pain, erythema and swelling. Any = occurrence of the symptom regardless of intensity grade. Any erythema/swelling = erythema/swelling spreading beyond 20 millimeters (mm) of injection site.

End point type	Primary

End point timeframe:

During the 7-day (Days 1-7) follow-up period after first vaccine dose

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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	46
Units: Participants				
Erythema	1	3	2	2
Pain	34	42	37	39
Swelling	4	2	2	4

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	45	47
Units: Participants				
Erythema	1	3	1	0
Pain	40	42	16	13
Swelling	3	2	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	45		
Units: Participants				
Erythema	1	0		
Pain	15	35		
Swelling	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited local AEs after second dose administration

End point title	Number of subjects with solicited local AEs after second dose administration[2]

End point description:

Assessed solicited local symptoms are pain, erythema and swelling. Any = occurrence of the symptom regardless of intensity grade. Any erythema/swelling = erythema/swelling spreading beyond 20 millimeters (mm) of injection site.

End point type	Primary

End point timeframe:

During the 7-day (Days 1-7) follow-up period after second vaccine dose

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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	37	36	41
Units: Participants				
Erythema	0	0	1	0
Pain	5	2	29	2
Swelling	0	0	4	0

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	37	38	39
Units: Participants				
Erythema	0	0	0	0
Pain	8	32	4	5
Swelling	0	2	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	39		
Units: Participants				
Erythema	0	0		
Pain	12	10		
Swelling	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited local AEs after booster dose administration

End point title	Number of subjects with solicited local AEs after booster dose administration[3]

End point description:

Assessed solicited local symptoms are pain, erythema and swelling. Any = occurrence of the symptom regardless of intensity grade. Any erythema/swelling = erythema/swelling spreading beyond 20 mm of injection site.

End point type	Primary

End point timeframe:

During the 7-day (Days 1-7) follow-up period after booster vaccine dose

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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	32	27	30
Units: Participants				
Erythema	1	1	0	0
Pain	27	31	26	29
Swelling	2	2	0	1

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	30	24	32
Units: Participants				
Erythema	1	1	0	0
Pain	28	25	4	10
Swelling	1	1	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	31		
Units: Participants				
Erythema	0	0		
Pain	13	21		
Swelling	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited general AEs after first dose administration

End point title	Number of subjects with solicited general AEs after first dose administration[4]

End point description:

Assessed solicited general symptoms are arthralgia, fatigue, gastrointestinal symptoms, headache, myalgia, shivering and fever [defined as oral temperature equal to or above 38.0 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade

End point type	Primary

End point timeframe:

During the 7-day (Days 1-7) follow-up period after first vaccine dose

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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	46
Units: Participants				
Arthralgia	4	6	9	2
Fatigue	17	18	22	18
Gastrointestinal symptoms	6	7	10	6
Headache	18	18	19	23
Myalgia	16	13	19	17
Shivering	6	3	10	10
Temperature	1	1	0	2

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	45	47
Units: Participants				
Arthralgia	3	8	6	5
Fatigue	21	18	17	19

Gastrointestinal symptoms	8	8	6	8
Headache	16	26	16	19
Myalgia	19	20	9	9
Shivering	8	9	2	2
Temperature	2	1	1	1

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	46		
Units: Participants				
Arthralgia	2	5		
Fatigue	12	12		
Gastrointestinal symptoms	10	8		
Headache	15	14		
Myalgia	6	11		
Shivering	2	3		
Temperature	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited general AEs after second dose administration

End point title	Number of subjects with solicited general AEs after second dose administration[5]

End point description:

Assessed solicited general symptoms are arthralgia, fatigue, gastrointestinal symptoms, headache, myalgia, shivering and fever [defined as oral temperature equal to or above 38.0 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade

End point type	Primary

End point timeframe:

During the 7-day (Days 1-7) follow-up period after second vaccine dose

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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	37	36	41
Units: Participants				
Arthralgia	3	4	4	0
Fatigue	7	7	10	6
Gastrointestinal symptoms	3	4	4	3

Headache	8	12	13	7
Myalgia	5	6	12	1
Shivering	2	4	4	0
Temperature	1	2	0	0

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	39	38	39
Units: Participants				
Arthralgia	4	4	0	0
Fatigue	7	8	5	5
Gastrointestinal symptoms	3	6	1	4
Headache	9	12	5	12
Myalgia	4	16	3	2
Shivering	3	5	1	0
Temperature	1	2	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: Participants				
Arthralgia	2	2		
Fatigue	10	5		
Gastrointestinal symptoms	2	2		
Headache	8	7		
Myalgia	6	3		
Shivering	2	1		
Temperature	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited general AEs after booster dose administration

End point title	Number of subjects with solicited general AEs after booster dose administration[6]

End point description:

Assessed solicited general symptoms are arthralgia, fatigue, gastrointestinal symptoms, headache, myalgia, shivering and fever [defined as oral temperature equal to or above 38.0 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade.

End point type	Primary

End point timeframe:

During the 7-day (Days 1-7) follow-up period after booster vaccine dose

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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	32	27	30
Units: Participants				
Arthralgia	6	8	4	4
Fatigue	15	19	17	16
Gastrointestinal symptoms	3	8	8	5
Headache	9	13	14	15
Myalgia	15	17	15	15
Shivering	5	13	6	6
Temperature	2	3	1	4

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	30	24	32
Units: Participants				
Arthralgia	9	4	1	1
Fatigue	20	9	2	6
Gastrointestinal symptoms	6	5	1	2
Headache	16	15	3	7
Myalgia	13	10	0	4
Shivering	14	9	0	1
Temperature	2	1	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	31		
Units: Participants				
Arthralgia	2	1		
Fatigue	6	3		
Gastrointestinal symptoms	4	0		
Headache	6	4		
Myalgia	5	3		
Shivering	2	1		
Temperature	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any unsolicited AEs post-vaccination period

End point title	Number of subjects with any unsolicited AEs post-vaccination period[7]

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any is defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination

End point type	Primary

End point timeframe:

During the 28-day (Days 1-28) follow-up period accross doses

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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	47	47
Units: Participants	27	23	23	24

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	47	48
Units: Participants	24	17	22	23

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	47		
Units: Participants	22	21		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with change from baseline in hematological and biochemical laboratory results at Day 8 by toxicity grading

End point title	Number of subjects with change from baseline in hematological and biochemical laboratory results at Day 8 by toxicity grading[8]

End point description:

Hematological parameters assessed are: Eosinophils increase [EOSi], hemoglobin decrease [HEMd] , lymphocytes decrease [LYMd], Neutrophils decrease [NEUd], platelets decrease [PLTCd], white blood cells decrease [WBCd], WBC increase [WBCi]. Biochemical parameters assessed are: alanine aminotransferase increase [ALTi], aspartate aminotransferase increase [ASTi], blood urea nitrogen [BUN], creatinine [CRE].Toxicity grading is according to the Food and Drug Administration (FDA) guidance for industry: Toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical Trials (September 2007). Category naming has been defined as follows: Parameter-grading at Baseline-grading at Timing: e.g.: "ALTi-G0-G1" (with G=Grade and UNK= Unknown).

End point type	Primary

End point timeframe:

At Day 8

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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	46
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi,G0,UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	3
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	40	45	42	41
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	0	1	1	0
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	1
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	3	0	1	1
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	1	0	1	0
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	3
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	44	46	44	42

ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	1
ASTi, G1, G0 (N=0;0;0;0;0;1;1;0;0;0)	0	0	0	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	0
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	3
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	43	46	45	43
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	1	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	0	3
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	44	46	45	43
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	3	1
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	2	0	2	1
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	41	43	38	43
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	0	1	1	0
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	1	1	1
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1	0	0
HEMd, G0, UNK (N=39;41;42;42;44;43;39;42;43;43)	1	0	1	1
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	37	37	40	39
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	1	4	1	1
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	1
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	3	1	2	4
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	2	0	0
HEMd, G2, G1 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	2	0	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	0
HEMd, G3, UNK (N=0;1;0;0;0;0;0;1;0;0)	0	0	0	0
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	1	0	0
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	3	1
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	2	0	2	1
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	39	45	37	44
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	2	0	0	0

LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	2	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	3	1
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	2	0	2	1
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	37	40	39	41
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	2	1	0	1
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	0	0	0	1
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	1	4	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	0	0	0
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	0	0	0	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	1	0
NEUd, G3, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	1	0	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	1	0	2	1
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	43	45	42	43
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	0
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G1 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	1	0	2	1
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	45	42	44
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	1	0	0	1
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0	1	0
WBCd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	1	0	2	1
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	41	43	42	42
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	1
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	2	0	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	0	1	1
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	44	47
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ALTi,G0,UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	1	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	45	45	43	44
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	1	0	0	2
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	1	0	1
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	46	45	42	44
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	2
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G1, G0 (N=0;0;0;0;0;1;1;0;0;0)	0	1	1	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	1
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	1	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	46	46	43	47
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	0	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	1	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	46	46	43	47
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	1	2
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	2	2
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	45	44	40	43
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	0	1	2	0
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	0	1	0

HEMd, G0, UNK (N=39;41;42;42;44;43;39;42;43;43)	0	0	1	1
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	43	40	37	40
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	1	3	1	1
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	0
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	1	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	1	2
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	1	2	0
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	1	0	0
HEMd, G2, G1 (N=2;0;1;0;2;1;1;2;2;0)	0	0	1	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	2	1	0	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	2
HEMd, G3, UNK (N=0;1;0;0;0;0;0;1;0;0)	0	0	0	1
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0	0	0
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	1	2
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	2	2
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	43	45	42	42
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	1	0	0	1
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	1	2
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	2	2
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	41	43	39	38
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	0	0	1	1
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	0	1	1	0
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	1	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	2	0	1	2
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	0	0	0	0
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	1	0	0	2
NEUd, G3, G0 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	0	1	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	2	2
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	46	45	42	44
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	1	0	0
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0

PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G1 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	0
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	2	2
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	44	46	41	42
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	0	0	1	0
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0	0	3
WBCd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	2	2
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	45	45	39	39
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	0	1	1	3
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	0	1	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	0	0	1	2
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	46		
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0		
ALTi,G0,UNK (N=40;46;43;45;45;45;44;44;43;46)	0	1		
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	41	44		
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	2	1		
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	2	0		
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	0		
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	1		
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	44	44		
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	1	1		

ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G1, G0 (N=0;0;0;0;0;1;1;0;0;0)	0	0		
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0		
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	1		
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	43	45		
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	1	0		
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	1		
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	45	45		
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	5	2		
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	1	2		
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	38	41		
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	1	0		
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0		
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	1	1		
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1		
HEMd, G0, UNK (N=39;41;42;42;44;43;39;42;43;43)	1	2		
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	40	40		
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	2	1		
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0		
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	1		
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	1	1		
HEMd, G2, G1 (N=2;0;1;0;2;1;1;2;2;0)	0	0		
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	2	0		
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0		
HEMd, G3, UNK (N=0;1;0;0;0;0;0;1;0;0)	0	0		
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0		
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	5	2		
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	1	2		
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	38	41		
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	0	1		
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	2	0		
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0		

NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	2	1		
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	2	1		
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	1	2		
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	37	37		
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	0	2		
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	0		
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	1	1		
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	0	0		
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	0	0		
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	1	2		
NEUd, G3, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	1	1		
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	1	2		
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	43	43		
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G1, G1 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	2	1		
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	1	2		
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	43		
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	0	0		
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	2	0		
WBCd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	2	1		
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	1	2		
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	38	39		
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	1	3		
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	2	0		
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	1		
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with change in hematological and biochemical laboratory results from Day 8 to Day 29 versus baseline by toxicity grading

End point title	Number of subjects with change in hematological and biochemical laboratory results from Day 8 to Day 29 versus baseline by toxicity grading[9]

End point description:

Hematological parameters assessed are: Eosinophils increase [EOSi], hemoglobin decrease [HEMd], lymphocytes decrease [LYMd], Neutrophils decrease [NEUd], platelets decrease [PLTCd], white blood cells decrease [WBCd], WBC increase [WBCi]. Biochemical parameters assessed are: alanine aminotransferase increase [ALTi], aspartate aminotransferase increase [ASTi], blood urea nitrogen [BUN], creatinine [CRE].Toxicity grading is according to the FDA guidance for industry: Toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical Trials (September 2007). Category naming has been defined as follows: Parameter-grading at Baseline-grading at Timing: e.g.: "ALTi-G0-G1" (with G=Grade and UNK=Unknown). The reported results consider any change that occurred during the defined time frame: i.e. any abnormality occurring at an intermediate visit leading to a maximum change from baseline, during the period covered, is the reported result for the outcome.

End point type	Primary

End point timeframe:

From Day 8 to Day 29

Notes:

[9] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	46
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	40	45	41	44
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	0	1	2	0
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	1
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	3	0	1	1
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	1	0	1	0
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	44	46	44	45
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	1

ASTi, G1, G0 (N=0;0;0;0;0;1;1;0;0;0)	0	0	0	0
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	0	0	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	0
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	43	45	45	46
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	0	1	0	0
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	1	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	0	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	44	46	45	46
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	3	1
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	0	0
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	43	43	40	44
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	0	1	1	0
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	1	1
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	1	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1	0	0
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	37	37	41	38
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	2	4	1	3
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	1
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	3	1	2	4
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	2	0	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	2	0	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	0
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	1	0	0
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	0	1	3	1
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0	0	0
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	0	0
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	41	45	39	45
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	2	0	0	0
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	0	0	0	0
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0

LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	0	1	3	1
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0	0	0
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	0	0
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	38	39	40	40
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	3	2	1	2
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	0	0	0	1
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	0	0	1
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	1	3	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	1	0	0
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	0	0	0	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	1	0
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G3, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	1	0	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	43	45	44	44
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	1	0	0	0
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	0
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G2 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	0	0	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	0	0
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	44	44	43
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	2	1	0	3
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0	1	0
WBCd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	42	40	43	42

WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	0	3	1	2
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	0	0	0	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	2	1	1
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	1	0	0	0
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	44	47
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	1	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	45	44	41	43
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	0	1	2	0
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	1
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	1	0	0	2
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	1	0	1
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	46	44	42	43
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	0	1	0	3
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G1, G0 (N=0;0;0;0;0;1;1;0;0;0)	0	0	1	0
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	1	0	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	1
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	1	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	46	46	43	47
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	0	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	1	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	46	46	43	47

EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	0	2
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	1	0
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	1	0
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	45	44	40	45
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	0	1	3	0
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	0	1	0
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	43	40	37	39
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	1	3	2	3
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	0
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	1	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	1	2
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	1	2	0
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	1	0	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	2	1	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	2
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0	0	1
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	1	2
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	1	0
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	42	45	43	43
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	1	0	0	2
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	1	0	0	0
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	1	2
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	1	0
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	40	42	37	38
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	1	1	2	3
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	0	1	3	0
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	0	0	0

NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	1	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	0	1	1
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	1	0	0	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	1
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	1	0	0	1
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G3, G0 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	0	1	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	0
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	46	45	43	46
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	1	0	0
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G2 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	0
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	0	0	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	1	0
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	43	46	42	44
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	1	0	1	0
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0	0	3
WBCd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	1	0
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	45	45	38	39
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	0	1	3	5
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	0	1	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	0	0	1	2
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	0	0	0	0
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	46		
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		

ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0		
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	40	44		
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	3	2		
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	2	0		
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	0		
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	42	45		
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	2	0		
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	1	1		
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G1, G0 (N=0;0;0;0;0;1;1;0;0;0)	0	0		
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	0		
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0		
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	43	46		
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	1	0		
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0		
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	45	46		
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	5	2		
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0		
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0		
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	39	43		
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	1	0		
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0		
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	1	1		
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1		
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	39	42		
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	4	1		

HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0		
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	1		
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	1	1		
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	2	0		
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0		
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0		
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	5	2		
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0		
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	39	41		
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	0	3		
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	2	0		
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	2	1		
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	2	0		
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	1	1		
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0		
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	38	38		
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	0	2		
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	1		
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	0		
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	0		
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	1		
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	0	0		
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	1	1		
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0		
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	0	1		
NEUd, G3, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	1	1		
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	44	45		
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0		

PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G1, G2 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	1	0		
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	1	1		
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0		
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	42		
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	1	3		
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	2	0		
WBCd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	2	1		
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0		
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	39	41		
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	1	3		
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	2	0		
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	1		
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	0	0		
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with change in hematological and biochemical laboratory results from Day 8 to Day 85 versus baseline by toxicity grading

End point title	Number of subjects with change in hematological and biochemical laboratory results from Day 8 to Day 85 versus baseline by toxicity grading[10]

End point description:

Hematological parameters assessed are: Eosinophils increase [EOSi], hemoglobin decrease [HEMd], lymphocytes decrease [LYMd], Neutrophils decrease [NEUd], platelets decrease [PLTCd], white blood cells decrease [WBCd], WBC increase [WBCi]. Biochemical parameters assessed are: alanine aminotransferase increase [ALTi], aspartate aminotransferase increase [ASTi], blood urea nitrogen [BUN], creatinine [CRE].Toxicity grading is according to the FDA guidance for industry: Toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical Trials (September 2007). Category naming has been defined as follows: Parameter-grading at Baseline-grading at Timing: e.g.: "ALTi-G0-G1" (with G=Grade and UNK= Unknown). The reported results consider any change that occurred during the defined time frame: i.e. any abnormality occurring at an intermediate visit leading to a maximum change from baseline, during the period covered, is the reported result for the outcome.

End point type	Primary

End point timeframe:

From Day 8 to Day 85

Notes:

[10] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	46
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	39	42	39	42
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	0	4	4	2
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	1	0	0	1
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	3	0	1	1
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	1	0	1	0
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	43	44	43	45
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	0	2	2	0
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	1	0	0	1
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	0	0	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	0
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	42	45	45	44
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	1	1	0	1
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	1
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	1	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	0	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	44	46	45	46
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	3	1
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0

EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	0	0
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	43	40	39	44
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	0	4	2	0
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	1	1
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	1	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1	0	0
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	37	34	41	35
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	2	7	1	6
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	1
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	2	1	1	3
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	1	2	1	1
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	1	0	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	1	0	0	0
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	1	0	0
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	0	1	3	1
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0	0	0
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	0	0
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	41	41	39	44
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	2	1	0	1
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	0	2	0	0
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	1	0	0
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	0	1	2	0
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0	1	1
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	0	0
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	37	35	40	36
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	4	4	1	4
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	0	1	0	2
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	1	0	2

NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	1	2	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	2	0	0
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	0	0	0	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	1	0
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	1	0	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	42	45	44	43
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	2	0	0	0
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	1
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	0	0	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	0	0
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	43	44	41
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	2	2	0	5
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	0	0	0	0
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0	1	0
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	0	0	0	0
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	41	39	42	39
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	1	4	2	5
WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	0	0	0	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	2	1	1
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	1	0	0	0
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	44	47
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	1	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	44	42	39	39
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	0	3	4	4
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	1	0	0	1
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	1	0	0	2
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	1	0	1
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	43	43	39	43
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	2	2	3	3
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	1	0	0	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	1	1	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	1
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	1	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	45	45	43	46
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	1	1	0	1
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	0	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	1	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	46	46	43	47
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	0	2
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	1	0
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	1	0
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	45	44	40	43
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	0	1	3	2
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0

HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	0	1	0
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	42	37	37	39
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	2	6	2	3
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	0
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	1	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	2
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	1	2	0
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	1	1	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	2	1	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	2
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0	0	1
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	1	2
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	1	0
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	40	44	43	41
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	3	1	0	4
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	1	0	0	0
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	0	0	0
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	0	1	1
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	1	0	0
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	1
NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	1	0
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	37	39	37	35
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	2	4	2	4
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	1	3	1
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	1	0	0	1
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	1	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	0	0	1
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	1	0	1	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	2
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	1	0	0	0
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0

PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	0	1	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	0
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	46	45	43	45
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	1	0	1
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	0
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	0	0	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	1	0
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	46	42	42
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	2	0	1	2
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	1	0	0	0
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0	0	2
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	0	0	0	1
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	1	0
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	45	44	36	39
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	0	2	5	5
WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	0	0	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	0	0	2	2
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	0	0	0	0
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	46		
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0		
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0		

ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	35	43		
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	8	3		
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	2	0		
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	0		
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	40	45		
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	4	0		
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	1	1		
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	0		
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0		
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	42	45		
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	1	1		
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	1	0		
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0		
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	45	46		
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	5	2		
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0		
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0		
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	36	43		
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	4	0		
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0		
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	1	1		
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1		
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	39	40		
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	4	3		
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0		

HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	1		
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	1	1		
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	1	0		
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	1	0		
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0		
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	5	2		
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0		
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	38	40		
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	1	4		
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	2	0		
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G2, G0 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	2	1		
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	1	1		
NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0		
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	36	37		
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	2	3		
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	1		
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	0		
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	0		
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	1		
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	0	0		
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	1		
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0		
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	1	1		
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	1	1		
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	44	45		
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	0		

PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G2, G1 (N=0;0;0;0;0;0;0;1;0)	1	0		
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	1	0		
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	1	1		
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0		
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	40	41		
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	2	4		
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	0	0		
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	2	0		
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	0	0		
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	2	1		
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0		
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	38	39		
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	1	5		
WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	1	0		
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	0		
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	2	1		
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	0	0		
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with change in hematological and biochemical laboratory results from Day 8 to Month 14+28 days versus baseline by toxicity grading

End point title	Number of subjects with change in hematological and biochemical laboratory results from Day 8 to Month 14+28 days versus baseline by toxicity grading[11]

End point description:

Hematological parameters assessed are: Eosinophils increase [EOSi], hemoglobin decrease [HEMd], lymphocytes decrease [LYMd], Neutrophils decrease [NEUd], platelets decrease [PLTCd], white blood cells decrease [WBCd], WBC increase [WBCi]. Biochemical parameters assessed are: alanine aminotransferase increase [ALTi], aspartate aminotransferase increase [ASTi], blood urea nitrogen [BUN], creatinine [CRE].Toxicity grading is according to the FDA guidance for industry: Toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical Trials (September 2007). Category naming has been defined as follows: Parameter-grading at Baseline-grading at Timing: e.g.: "ALTi-G0-G1" (with G=Grade and UNK= Unknown). The reported results

consider any change that occurred during the defined time frame: i.e. any abnormality occurring at an intermediate visit leading to a maximum change from baseline, during the period covered, is the reported result for the outcome.

End point type	Primary

End point timeframe:

From Day 8 to Month 14 + 28 days

Notes:

[11] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	46
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	38	38	39	42
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	1	8	3	2
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0	1	0
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	1	0	0	1
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	3	0	1	1
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	1	0	1	0
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	42	43	41	44
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	1	3	3	1
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	1	0	0	1
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	0	0	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	0
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	41	45	45	44
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	1	1	0	0
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	1	0	0	1
BUN, G0, G3 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	1
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	1	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	0	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	44	46	45	46
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	3	1
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	0	0
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	42	40	39	43
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	1	4	2	1
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	1	1
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	1	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1	0	0
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	35	33	39	33
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	4	8	3	8
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	1
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	2	1	1	3
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	2	1	1
HEMd, G1, G3 (N=3;3;2;4;0;2;4;2;1;2)	1	0	0	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	1	0	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	0
HEMd, G2, G4 (N=2;0;1;0;2;1;1;2;2;0)	1	0	0	0
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	1	0	0
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	0	0	3	1
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	1	0	0
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	0	0
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	40	41	39	44
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	3	1	0	1
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	0	2	0	0
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	1	0	0
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	0	1	2	0
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0	1	1
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0

NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	0	0
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	36	34	37	35
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	5	4	2	5
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	0	2	2	2
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	1	0	2
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	1	2	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	0	2	0	0
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	1	0	0	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	1	0
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	1	0	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	42	45	44	43
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	2	0	0	0
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	1
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G2, G2 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	0	0	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	0	0
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	42	41	40
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	2	3	3	6
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	0	0	0	0
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	0	0	1	0
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	1	0	0	0
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	39	39	40	37
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	3	4	4	6
WBCi, G0, G2 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	1

WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	0	0	0	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	2	1	1
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	1	0	0	0
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	44	47
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	1	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	40	41	38	39
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	4	3	5	4
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	1	1	0	1
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	1	0	0	2
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	1	0	1
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	42	43	37	42
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	3	2	5	4
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	1	0	0	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	1	1	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	1
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	1	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	45	45	42	46
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	1	1	1	1
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G0, G3 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	0	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0

CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	1	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	46	46	43	47
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	0	2
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	1	0
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	1	0
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	45	44	39	42
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	0	1	4	3
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	0	1	0
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	39	37	35	36
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	5	5	3	6
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	1	1	0
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	1	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	2
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	1	2	0
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	1	1	0
HEMd, G1, G3 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	1	1	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	1	0	0	2
HEMd, G2, G4 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	0
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0	0	1
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	1	2
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	1	0
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	40	44	43	38
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	3	1	0	7
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	1	0	0	0
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	0	0	0
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	0	1	1
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	1	0	0
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	1

NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	1	0
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	36	38	34	35
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	3	5	5	4
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	1	3	1
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	1	0	0	1
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	1	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	0	0	1
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	1	0	1	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	2
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	1	0	0	0
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	0	1	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	0
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	46	45	43	45
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	1	0	1
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	0
PLTCd, G2, G2 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	0	0	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	1	0
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	46	42	41
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	2	0	1	3
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	1	0	0	0
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0	0	2
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	0	0	0	1
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	1	0
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	43	43	35	37
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	2	3	5	6
WBCi, G0, G2 (N=42;43;44;44;45;46;42;44;40;44)	0	0	1	1

WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	0	0	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	0	0	2	2
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	0	0	0	0
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	46		
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0		
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	30	40		
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	13	6		
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	2	0		
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	0		
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ASTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0		
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	37	43		
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	7	2		
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	1	1		
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	0		
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0		
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	41	45		
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	2	1		
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G0, G3 (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G1, G0 (N=1;0;0;0;0;0;0;0;1;0)	1	0		
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		

CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0		
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	45	46		
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	5	2		
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0		
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0		
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	34	43		
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	6	0		
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0		
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	1	1		
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1		
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	39	39		
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	4	4		
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0		
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	1		
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	1	1		
HEMd, G1, G3 (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	1	0		
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	1	0		
HEMd, G2, G4 (N=2;0;1;0;2;1;1;2;2;0)	0	0		
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0		
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	4	2		
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	38	40		
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	1	4		
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	2	0		
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	2	1		
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	1	1		

NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0		
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	34	34		
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	4	6		
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	1		
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	0		
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	0		
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	0	1		
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	1	0		
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	1		
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0		
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	1	1		
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	1	1		
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	44	45		
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G2, G2 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	1	0		
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	1	1		
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0		
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	38	41		
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	4	4		
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	0	0		
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	2	0		
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	0	0		
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	2	1		
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0		
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	36	36		
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	3	7		
WBCi, G0, G2 (N=42;43;44;44;45;46;42;44;40;44)	0	1		

WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	1	0		
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	0		
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	1		
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	1	0		
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with change in hematological and biochemical laboratory results from Day 8 to Month 26 versus baseline by toxicity grading

End point title	Number of subjects with change in hematological and biochemical laboratory results from Day 8 to Month 26 versus baseline by toxicity grading[12]

End point description:

Hematological parameters assessed are: Eosinophils increase [EOSi], hemoglobin decrease [HEMd], lymphocytes decrease [LYMd], Neutrophils decrease [NEUd], platelets decrease [PLTCd], white blood cells decrease [WBCd], WBC increase [WBCi]. Biochemical parameters assessed are: alanine aminotransferase increase [ALTi], aspartate aminotransferase increase [ASTi], blood urea nitrogen [BUN], creatinine [CRE].Toxicity grading is according to the FDA guidance for industry: Toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical Trials (September 2007). Category naming has been defined as follows: Parameter-grading at Baseline-grading at Timing: e.g.: "ALTi-G0-G1" (with G=Grade and UNK= Unknown). The reported results consider any change that occurred during the defined time frame: i.e. any abnormality occurring at an intermediate visit leading to a maximum change from baseline, during the period covered, is the reported result for the outcome.

End point type	Primary

End point timeframe:

From Day 8 to Month 26

Notes:

[12] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	46
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	38	38	39	42
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	1	8	3	2
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0	1	0
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	1	0	0	1
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	2	0	1	1
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	2	0	1	0

ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	42	42	41	44
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	1	4	3	1
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	1	0	0	1
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	0	0	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	0
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	40	45	45	44
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	2	1	0	0
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	1	0	0	1
BUN, G0, G3 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	1
BUN, G1, G0 (N=1; 0;0;0;0;0;0;0;1;0)	1	0	0	0
BUN, G1, G1 (N=1;0;0;0;0;0;0;0;1;0)	0	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	0	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	44	46	45	46
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	3	1
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	0	0
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	42	40	39	43
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	1	4	2	1
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	1	1
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	1	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1	0	0
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	33	32	37	31
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	5	9	5	7
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	1	0	0	4
HEMd, G0, G3 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	0
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	2	1	1	3

HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	2	1	1
HEMd, G1, G3 (N=3;3;2;4;0;2;4;2;1;2)	1	0	0	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	1	0	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	0
HEMd, G2, G4 (N=2;0;1;0;2;1;1;2;2;0)	1	0	0	0
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	1	0	0
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	0	0	3	1
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	1	0	0
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	0	0
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	39	40	39	44
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	4	1	0	1
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	0	3	0	0
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	1	0	0
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	1	0
LYMd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	0	1	2	0
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0	1	1
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	0	0
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	35	34	37	35
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	5	4	2	5
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	2	2	2
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	1	0	2
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	1	2	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	0	2	0	0
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	1	0	0	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	1	0
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	1	0	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	0	0
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	42	45	44	43
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	2	0	0	0
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	1

PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G2, G2 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	0	0	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	0	0
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	39	42	41	40
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	4	3	3	6
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	0	0	0	0
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	0	0	1	0
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	1	0	0	0
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	1	0	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	37	38	40	37
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	5	5	4	6
WBCi, G0, G2 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	1
WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	0	0	0	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	2	1	1
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	1	0	0	0
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	44	47
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0	1	0
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	40	39	37	38
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	4	5	6	5
ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	1	1	0	1
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0	0	0

ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	1	0	0	2
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	0	1	0	1
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	0	0
ASTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0	1	0
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	42	42	36	42
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	3	1	6	4
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	1	2	0	0
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0	0	0
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	1	1	0
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0	0	1
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0	1	0
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	45	45	42	46
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	1	1	1	1
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G0, G3 (N=43;46;45;46;46;46;44;47;43;46)	0	0	0	0
BUN, G1, G0 (N=1; 0;0;0;0;0;0;0;1;0)	0	0	0	0
BUN, G1, G1 (N=1;0;0;0;0;0;0;0;1;0)	0	0	0	0
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	0	0	1	0
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0	1	0
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	46	46	43	47
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	0	2
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	1	0
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0	1	0
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	45	44	38	41
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	0	1	5	4
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	0	0	0	0
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	0	1	0
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	38	36	35	35
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	6	6	3	6
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	1	1	1
HEMd, G0, G3 (N=39;41;42;42;44;43;39;42;43;43)	0	0	0	0
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0	1	0

HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	2
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	1	2	0
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	0	1	1	0
HEMd, G1, G3 (N=3;3;2;4;0;2;4;2;1;2)	0	0	0	0
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	1	1	1	0
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	1	0	0	2
HEMd, G2, G4 (N=2;0;1;0;2;1;1;2;2;0)	0	0	0	0
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0	0	1
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	1	1	2
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0	1	0
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	40	44	43	37
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	3	1	0	8
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	1	0	0	0
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	0	0	0
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0	0	0
LYMd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	1	0	1	1
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	1	0	0
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	1
NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	0	0	0	0
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0	1	0
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	36	36	34	35
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	3	6	5	4
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	2	3	1
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	1	0	0	1
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	1	0	0
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	1	0	0	1
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	1	0	1	1
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	0
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0	0	2
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	1	0	0	0
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	0	0	1	0
PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0	1	0
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	46	44	43	45

PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	1	0	1
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	1	0	0
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	1
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0	0	0
PLTCd, G2, G2 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	0	0	0	0
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0	1	0
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	41	46	42	41
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	2	0	1	3
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	1	0	0	0
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0	0	2
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	0	0	0	1
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	1	0	0	0
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	0	0	1	0
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0	1	0
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	43	43	35	37
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	2	3	5	6
WBCi, G0, G2 (N=42;43;44;44;45;46;42;44;40;44)	0	0	1	1
WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	0	0	0	0
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	0	0	1
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	0	0	2	2
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	0	0	0	0
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	0	0	0	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	46		
Units: Participants				
ALTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ALTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0		
ALTi, G0, UNK (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G0, G0 (N=40;46;43;45;45;45;44;44;43;46)	29	40		
ALTi, G0, G1 (N=40;46;43;45;45;45;44;44;43;46)	14	6		

ALTi, G0, G2 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G0, G3 (N=40;46;43;45;45;45;44;44;43;46)	0	0		
ALTi, G1, G0 (N=4;0;2;1;1;1;0;3;2;0)	1	0		
ALTi, G1, G1 (N=4;0;2;1;1;1;0;3;2;0)	1	0		
ASTi, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
ASTi, UNK, G1 (N=0;0;0;0;0;0;1;0;1;0)	0	0		
ASTi, G0, UNK (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G0, G0 (N=44;46;45;46;46;45;43;46;45;46)	37	43		
ASTi, G0, G1 (N=44;46;45;46;46;45;43;46;45;46)	7	2		
ASTi, G0, G2 (N=44;46;45;46;46;45;43;46;45;46)	1	1		
ASTi, G0, G4 (N=44;46;45;46;46;45;43;46;45;46)	0	0		
ASTi, G1, G1 (N=0;0;0;0;0;1;1;0;0;0)	0	0		
ASTi, G2, G0 (N=0;0;0;0;0;0;0;1;0;0)	0	0		
BUN, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
BUN, G0, UNK (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G0, G0 (N=43;46;45;46;46;46;44;47;43;46)	41	45		
BUN, G0, G1 (N=43;46;45;46;46;46;44;47;43;46)	2	1		
BUN, G0, G2 (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G0, G3 (N=43;46;45;46;46;46;44;47;43;46)	0	0		
BUN, G1, G0 (N=1; 0;0;0;0;0;0;0;1;0)	0	0		
BUN, G1, G1 (N=1;0;0;0;0;0;0;0;1;0)	1	0		
BUN, G2, G0 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
CRE, UNK, G0 (N=0;0;0;0;0;0;1;0;1;0)	1	0		
CRE, G0, UNK (N=44;46;45;46;46;46;44;47;45;46)	0	0		
CRE, G0, G0 (N=44;46;45;46;46;46;44;47;45;46)	45	46		
EOSi, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	5	2		
EOSi, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	0	0		
EOSi, G0, UNK (N=43;44;41;44;45;45;44;45;40;43)	0	0		
EOSi, G0, G0 (N=43;44;41;44;45;45;44;45;40;43)	34	42		
EOSi, G0, G1 (N=43;44;41;44;45;45;44;45;40;43)	6	1		
EOSi, G1, G0 (N=0;1;1;1;0;0;0;0;1;1)	0	0		
EOSi, G1, G1 (N=0;1;1;1;0;0;0;0;1;1)	1	1		
HEMd, UNK, G0 (N=0;1;0;0;0;0;1;0;0;1)	0	1		
HEMd, G0, G0 (N=39;41;42;42;44;43;39;42;43;43)	37	39		
HEMd, G0, G1 (N=39;41;42;42;44;43;39;42;43;43)	5	4		
HEMd, G0, G2 (N=39;41;42;42;44;43;39;42;43;43)	0	0		

HEMd, G0, G3 (N=39;41;42;42;44;43;39;42;43;43)	1	0		
HEMd, G1, UNK (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G0 (N=3;3;2;4;0;2;4;2;1;2)	0	1		
HEMd, G1, G1 (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G1, G2 (N=3;3;2;4;0;2;4;2;1;2)	1	1		
HEMd, G1, G3 (N=3;3;2;4;0;2;4;2;1;2)	0	0		
HEMd, G2, G2 (N=2;0;1;0;2;1;1;2;2;0)	1	0		
HEMd, G2, G3 (N=2;0;1;0;2;1;1;2;2;0)	1	0		
HEMd, G2, G4 (N=2;0;1;0;2;1;1;2;2;0)	0	0		
HEMd, G3, G3 (N=0;1;0;0;0;0;0;1;0;0)	0	0		
LYMd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	4	2		
LYMd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
LYMd, G0, UNK (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G0, G0 (N=43;45;39;45;44;45;44;45;39;44)	38	40		
LYMd, G0, G1 (N=43;45;39;45;44;45;44;45;39;44)	1	4		
LYMd, G0, G2 (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G0, G3 (N=43;45;39;45;44;45;44;45;39;44)	0	0		
LYMd, G1, G0 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G1, G1 (N=0;0;3;0;0;0;0;0;2;0)	2	0		
LYMd, G1, G2 (N=0;0;3;0;0;0;0;0;2;0)	0	0		
LYMd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
NEUd, UNK, G0 (N=1;1;3;1;1;1;1;2;5;2)	2	1		
NEUd, UNK, G1 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
NEUd, UNK, G2 (N=1;1;3;1;1;1;1;2;5;2)	1	1		
NEUd, UNK, G3 (N=1;1;3;1;1;1;1;2;5;2)	1	0		
NEUd, G0, UNK (N=41;41;41;44;41;44;43;41;39;41)	0	0		
NEUd, G0, G0 (N=41;41;41;44;41;44;43;41;39;41)	34	34		
NEUd, G0, G1 (N=41;41;41;44;41;44;43;41;39;41)	4	6		
NEUd, G0, G2 (N=41;41;41;44;41;44;43;41;39;41)	1	1		
NEUd, G0, G3 (N=41;41;41;44;41;44;43;41;39;41)	0	0		
NEUd, G1, G0 (N=2;4;0;1;2;1;1;2;1;1)	0	0		
NEUd, G1, G1 (N=2;4;0;1;2;1;1;2;1;1)	0	1		
NEUd, G1, G2 (N=2;4;0;1;2;1;1;2;1;1)	1	0		
NEUd, G2, G0 (N=0;0;1;0;1;0;0;2;1;2)	0	1		
NEUd, G2, G1 (N=0;0;1;0;1;0;0;2;1;2)	0	0		
NEUd, G2, G2 (N=0;0;1;0;1;0;0;2;1;2)	1	1		
NEUd, G3, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
PLTCd, UNK, G0 (N=0;1;0;0;0;0;1;0;1;1)	1	1		

PLTCd, G0, UNK (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G0, G0 (N=44;45;45;44;46;46;44;46;44;45)	44	45		
PLTCd, G0, G1 (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G0, G2 (N=44;45;45;44;46;46;44;46;44;45)	0	0		
PLTCd, G1, G0 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G1, G3 (N=0;0;0;2;0;0;0;1;0;0)	0	0		
PLTCd, G2, G2 (N=0;0;0;0;0;0;0;0;1;0)	1	0		
WBCd, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	1	0		
WBCd, UNK, G1 (N=0;1;0;0;0;0;1;0;2;1)	1	1		
WBCd, G0, UNK (N=43;45;44;46;44;46;44;44;42;45)	0	0		
WBCd, G0, G0 (N=43;45;44;46;44;46;44;44;42;45)	38	41		
WBCd, G0, G1 (N=43;45;44;46;44;46;44;44;42;45)	4	4		
WBCd, G0, G2 (N=43;45;44;46;44;46;44;44;42;45)	0	0		
WBCd, G1, G0 (N=1;0;1;0;1;0;0;3;2;0)	1	0		
WBCd, G1, G1 (N=1;0;1;0;1;0;0;3;2;0)	1	0		
WBCd, G2, G1 (N=0;0;0;0;1;0;0;0;0;0)	0	0		
WBCi, UNK, G0 (N=0;1;0;0;0;0;1;0;2;1)	2	1		
WBCi, G0, UNK (N=42;43;44;44;45;46;42;44;40;44)	0	0		
WBCi, G0, G0 (N=42;43;44;44;45;46;42;44;40;44)	36	36		
WBCi, G0, G1 (N=42;43;44;44;45;46;42;44;40;44)	3	7		
WBCi, G0, G2 (N=42;43;44;44;45;46;42;44;40;44)	0	1		
WBCi, G0, G3 (N=42;43;44;44;45;46;42;44;40;44)	1	0		
WBCi, G1, G0 (N=2;2;1;2;1;0;2;3;3;1)	1	0		
WBCi, G1, G1 (N=2;2;1;2;1;0;2;3;3;1)	1	1		
WBCi, G1, G2 (N=2;2;1;2;1;0;2;3;3;1)	1	0		
WBCi, G2, G1 (N=0;0;0;0;0;0;0;0;1;0)	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any medically-attended adverse events (MAEs)

End point title	Number of subjects with any medically-attended adverse events (MAEs)[13]

End point description:

MAEs are defined as events for which the subject receives medical attention defined as hospitalization, an emergency room visit, or a visit to or from medical personnel (medical doctor) for any reason. Any

MAE(s) = Occurrence of any MAE(s) regardless of intensity grade or relation to vaccination.

End point type	Primary

End point timeframe:

During the entire study period (from Day 1 up to Month 26)

Notes:

[13] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	47	47
Units: Participants	21	16	20	23

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	47	48
Units: Participants	21	14	19	18

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	47		
Units: Participants	23	20		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects reporting any potential immune-mediated diseases (pIMDs)

End point title	Number of subjects reporting any potential immune-mediated diseases (pIMDs)[14]

End point description:

pIMDs are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune etiology.

End point type	Primary

End point timeframe:

During the entire study period (from Day 1 up to Month 26)

Notes:

[14] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	47	47
Units: Participants	0	0	0	0

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	47	48
Units: Participants	0	0	1	0

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	47		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events (SAEs).

End point title	Number of subjects with serious adverse events (SAEs).[15]

End point description:

SAEs include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Primary

End point timeframe:

During the entire study period (from Day 1 up to Month 26)

Notes:

[15] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	47	47
Units: Participants	2	1	1	2

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	47	48
Units: Participants	2	2	0	2

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	47		
Units: Participants	2	3		

Statistical analyses

No statistical analyses for this end point

Primary: Number of seropositive subjects for anti-H1 stalk antibodies measured by enzyme-linked immunosorbent assay (ELISA)– Day 1

End point title	Number of seropositive subjects for anti-H1 stalk antibodies measured by enzyme-linked immunosorbent assay (ELISA)– Day 1[16]

End point description:

Anti-H1 stalk immune response measured by ELISA. A seropositive subject is a subject whose concentration is greater than or equal to the cut-off value: ELISA cut-off = 66 ELISA.Unit per milliliter (EL.U/mL).

End point type	Primary

End point timeframe:

At Day 1

Notes:

[16] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	47	47
Units: Participants	45	46	47	47

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	47	46
Units: Participants	48	47	47	46

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	45		
Units: Participants	44	45		

Statistical analyses

No statistical analyses for this end point

Primary: Number of seropositive subjects for anti-H1 stalk antibodies measured by ELISA– Day 29

End point title	Number of seropositive subjects for anti-H1 stalk antibodies measured by ELISA– Day 29[17]

End point description:

Anti-H1 stalk immune response measured by ELISA. A seropositive subject is a subject whose concentration is greater than or equal to the cut-off value: ELISA cut-off = 66 EL.U/mL.

End point type	Primary

End point timeframe:

At Day 29

Notes:

[17] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	41	40
Units: Participants	43	40	41	40

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	37	41
Units: Participants	42	42	37	41

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Participants	39	40		

Statistical analyses

No statistical analyses for this end point

Primary: Number of seropositive subjects for anti-H1 stalk antibodies measured by ELISA– Day 85

End point title	Number of seropositive subjects for anti-H1 stalk antibodies measured by ELISA– Day 85[18]

End point description:

Anti-H1 stalk immune response measured by ELISA. A seropositive subject is a subject whose concentration is greater than or equal to the cut-off value: ELISA cut-off = 66 EL.U/mL.

End point type	Primary

End point timeframe:

At Day 85

Notes:

[18] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	36	34	35
Units: Participants	39	36	34	35

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	35	34	34
Units: Participants	39	35	34	34

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	38		
Units: Participants	35	38		

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations of serum H1 stalk antibodies measured by ELISA– Day 1

End point title	Concentrations of serum H1 stalk antibodies measured by ELISA– Day 1[19]

End point description:

Concentrations are presented as Geometric Mean Concentrations (GMCs) and measured by ELISA. ELISA cut-off = 66 EL.U/mL.

End point type	Primary

End point timeframe:

At Day 1

Notes:

[19] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	47	47
Units: EL.U/mL				
geometric mean (confidence interval 95%)	8887.9 (7004.9 to 11277.1)	8719.3 (6547.0 to 11612.3)	9691 (7593.7 to 12367.7)	9121 (7180.0 to 11586.6)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	47	46
Units: EL.U/mL				
geometric mean (confidence interval 95%)	9948.6 (8106.2 to 12209.8)	8555.5 (6980.1 to 10486.4)	9019.6 (7263.5 to 11200.2)	9278.2 (7430.7 to 11585.1)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	45		
Units: EL.U/mL				
geometric mean (confidence interval 95%)	9039.3 (6930.7 to 11789.5)	9160 (7225.7 to 11612.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations of serum H1 stalk antibodies measured by ELISA– Day 29

End point title	Concentrations of serum H1 stalk antibodies measured by ELISA– Day 29[20]

End point description:

Concentrations are presented as GMCs and measured by ELISA. ELISA cut-off = 66 EL.U/mL.

End point type	Primary

End point timeframe:

At Day 29

Notes:

[20] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	41	40
Units: EL.U/mL				
geometric mean (confidence interval 95%)	112973.2 (90888.2 to 140424.5)	45645 (35289.4 to 59039.5)	116596.8 (93869.6 to 144826.6)	61634.2 (49810.3 to 76264.7)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	37	41
Units: EL.U/mL				
geometric mean (confidence interval 95%)	46596.2 (38306.7 to 56679.5)	67114.6 (54649.7 to 82422.6)	35580.2 (24654.2 to 51348.2)	20398.6 (16362.4 to 25430.5)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: EL.U/mL				
geometric mean (confidence interval 95%)	36426.2 (29124.8 to 45558.0)	21938.1 (18037.8 to 26681.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations of serum H1 stalk antibodies measured by ELISA– Day 85

End point title	Concentrations of serum H1 stalk antibodies measured by ELISA– Day 85[21]

End point description:

Concentrations are presented as GMCs and measured by ELISA. ELISA cut-off = 66 EL.U/mL.

End point type	Primary

End point timeframe:

At Day 85

Notes:

[21] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	36	34	35
Units: EL.U/mL				
geometric mean (confidence interval 95%)	45351.6 (36766.7 to 55941.1)	28437.5 (21623.4 to 37398.9)	74639.7 (59986.3 to 92872.6)	30419.3 (23619.9 to 39176.0)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	35	34	34
Units: EL.U/mL				
geometric mean (confidence interval 95%)	25718.6 (20748.8 to 31878.8)	48775.9 (40697.7 to 58457.7)	28617.8 (19448.1 to 42110.9)	15105.9 (12007.7 to 19003.6)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	38		
Units: EL.U/mL				
geometric mean (confidence interval 95%)	37911.4 (30149.4 to 47671.7)	16749.9 (13471.8 to 20825.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of seropositive subjects for anti-H1 stalk antibodies measured by microneutralization (MN) assay – Day 1

End point title	Number of seropositive subjects for anti-H1 stalk antibodies measured by microneutralization (MN) assay – Day 1[22]

End point description:

Anti-H1 stalk immune response measured by MN are expressed in 1/DILUTION (DIL). The functionality of the stalk-reactive antibodies is evaluated by MN assays developed using chimeric viruses. A seropositive subject is a subject whose titer is greater than or equal to the cut-off value: MN cut-off = 20 1/DIL.

End point type	Primary

End point timeframe:

At Day 1

Notes:

[22] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	44	45	46
Units: Participants	32	34	35	36

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	43
Units: Participants	33	40	37	34

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: Participants	31	33		

Statistical analyses

No statistical analyses for this end point

Primary: Number of seropositive subjects for anti-H1 stalk antibodies measured by MN assay – Day 29

End point title	Number of seropositive subjects for anti-H1 stalk antibodies measured by MN assay – Day 29[23]

End point description:

Anti-H1 stalk immune response measured by MN are expressed in 1/DIL. The functionality of the stalk-reactive antibodies is evaluated by MN assays developed using chimeric viruses. A seropositive subject is a subject whose titer is greater than or equal to the cut-off value: MN cut-off = 20 1/DIL.

End point type	Primary

End point timeframe:

At Day 29

Notes:

[23] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	40	40
Units: Participants	43	40	40	40

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	42	37	41
Units: Participants	41	41	36	41

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Participants	37	40		

Statistical analyses

No statistical analyses for this end point

Primary: Number of seropositive subjects for anti-H1 stalk antibodies measured by MN assay – Day 85

End point title	Number of seropositive subjects for anti-H1 stalk antibodies measured by MN assay – Day 85[24]

End point description:

Anti-H1 stalk immune response measured by MN are expressed in 1/DIL. The functionality of the stalk-reactive antibodies is evaluated by MN assays developed using chimeric viruses. A seropositive subject is a subject whose titer is greater than or equal to the cut-off value: MN cut-off = 20 1/DIL.

End point type	Primary

End point timeframe:

At Day 85

Notes:

[24] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	36	34	33
Units: Participants	36	35	34	31

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	35	34	34
Units: Participants	38	35	30	32

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	38		
Units: Participants	35	37		

Statistical analyses

No statistical analyses for this end point

Primary: Titers for serum H1 stalk antibodies measured by MN assay – Day 1

End point title	Titers for serum H1 stalk antibodies measured by MN assay – Day 1[25]

End point description:

Titers are presented as GMTs and measured by MN assay. MN cut-off = 20 1/DIL.

End point type	Primary

End point timeframe:

At Day 1

Notes:

[25] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	44	45	46
Units: Titer				
geometric mean (confidence interval 95%)	40.6 (29.4 to 56.1)	45.4 (33.4 to 61.6)	45.9 (34.2 to 61.8)	45.8 (34.5 to 60.8)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	43
Units: Titer				
geometric mean (confidence interval 95%)	41.9 (30.7 to 57.3)	45.1 (35.0 to 58.2)	44.6 (34.4 to 57.7)	43.4 (32.4 to 58.0)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: Titer				
geometric mean (confidence interval 95%)	42.7 (31.2 to 58.6)	38 (28.8 to 50.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Titers for serum H1 stalk antibodies measured by MN assay – Day 29

End point title	Titers for serum H1 stalk antibodies measured by MN assay – Day 29[26]

End point description:

Titers are presented as GMTs and measured by MN assay. MN cut-off = 20 1/DIL.

End point type	Primary

End point timeframe:

At Day 29

Notes:

[26] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	40	40
Units: Titer				
geometric mean (confidence interval 95%)	100.3 (88.1 to 114.1)	109.3 (94.0 to 127.0)	113.1 (96.5 to 132.6)	105.6 (91.0 to 122.5)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	42	37	41
Units: Titer				
geometric mean (confidence interval 95%)	96.4 (83.2 to 111.6)	89.8 (73.0 to 110.5)	86.2 (69.9 to 106.3)	80 (66.6 to 96.1)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Titer				
geometric mean (confidence interval 95%)	74.5 (59.6 to 93.2)	87.2 (75.6 to 100.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Titers for serum H1 stalk antibodies measured by MN assay – Day 85

End point title	Titers for serum H1 stalk antibodies measured by MN assay – Day 85[27]

End point description:

Titers are presented as GMTs and measured by MN assay. MN cut-off = 20 1/DIL.

End point type	Primary

End point timeframe:

At Day 85

Notes:

[27] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	36	34	33
Units: Titer				
geometric mean (confidence interval 95%)	73 (58.3 to 91.5)	98.9 (81.5 to 119.9)	122.7 (108.9 to 138.3)	59.6 (45.9 to 77.4)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	35	34	34
Units: Titer				
geometric mean (confidence interval 95%)	87.4 (71.1 to 107.6)	109.8 (93.0 to 129.8)	55.4 (41.3 to 74.3)	75.3 (56.4 to 100.4)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	38		
Units: Titer				
geometric mean (confidence interval 95%)	88.3 (74.2 to 105.2)	86.1 (70.2 to 105.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody concentration measured by ELISA – Day 29

End point title	Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody concentration measured by ELISA – Day 29[28]

End point description:

Percentage of subjects with an equal or greater than (≥) 4-fold increase of anti-H1 stalk antibody concentration, from Day 1, is calculated with exact 95% CI by ELISA.

End point type	Primary

End point timeframe:

At Day 29, compared to pre-vaccination at Day 1

Notes:

[28] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	41	40
Units: Percentage of subjects				
number (confidence interval 95%)	88.4 (74.9 to 96.1)	60 (43.3 to 75.1)	87.8 (73.8 to 95.9)	70 (53.5 to 83.4)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	37	41
Units: Percentage of subjects				
number (confidence interval 95%)	52.4 (36.4 to 68.0)	83.3 (68.6 to 93.0)	35.1 (20.2 to 52.5)	24.4 (12.4 to 40.3)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Percentage of subjects				
number (confidence interval 95%)	38.5 (23.4 to 55.4)	15 (5.7 to 29.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody concentration measured by ELISA – Day 85

End point title	Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody concentration measured by ELISA – Day 85[29]

End point description:

Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody concentration, from Day 1, is calculated with exact 95% CI by ELISA.

End point type	Primary

End point timeframe:

At Day 85, compared to pre-vaccination at Day 1

Notes:

[29] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	36	34	35
Units: Percentage of subjects				
number (confidence interval 95%)	51.3 (34.8 to 67.6)	44.4 (27.9 to 61.9)	79.4 (62.1 to 91.3)	37.1 (21.5 to 55.1)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	35	34	34
Units: Percentage of subjects				
number (confidence interval 95%)	20.5 (9.3 to 36.5)	80 (63.1 to 91.6)	29.4 (15.1 to 47.5)	8.8 (1.9 to 23.7)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	38		
Units: Percentage of subjects				
number (confidence interval 95%)	37.1 (21.5 to 55.1)	7.9 (1.7 to 21.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk titer measured by MN assay – Day 29

End point title	Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk titer measured by MN assay – Day 29[30]

End point description:

Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody titer from Day 1, is calculated with exact 95% CI by MN assay.

End point type	Primary

End point timeframe:

At Day 29, compared to pre-vaccination at Day 1

Notes:

[30] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	38	38	39
Units: Percentage of subjects				
number (confidence interval 95%)	40.5 (25.6 to 56.7)	39.5 (24.0 to 56.6)	31.6 (17.5 to 48.7)	41 (25.6 to 57.9)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	41	35	38
Units: Percentage of subjects				
number (confidence interval 95%)	36.8 (21.8 to 54.0)	31.7 (18.1 to 48.1)	34.3 (19.1 to 52.2)	26.3 (13.4 to 43.1)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	36		
Units: Percentage of subjects				
number (confidence interval 95%)	29.7 (15.9 to 47.0)	36.1 (20.8 to 53.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk titer measured by MN assay – Day 85

End point title	Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk titer measured by MN assay – Day 85[31]

End point description:

Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody titer from Day 1, is calculated with exact 95% CI by MN assay.

End point type	Primary

End point timeframe:

At Day 85, compared to pre-vaccination at Day 1

Notes:

[31] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	34	32	33
Units: Percentage of subjects				
number (confidence interval 95%)	29.7 (15.9 to 47.0)	38.2 (22.2 to 56.4)	34.4 (18.6 to 53.2)	15.2 (5.1 to 31.9)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	34	33	32
Units: Percentage of subjects				
number (confidence interval 95%)	31.4 (16.9 to 49.3)	41.2 (24.6 to 59.3)	21.2 (9.0 to 38.9)	18.8 (7.2 to 36.4)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: Percentage of subjects				
number (confidence interval 95%)	33.3 (18.0 to 51.8)	41.2 (24.6 to 59.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration measured by ELISA – Day 29

End point title	Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration measured by ELISA – Day 29[32]

End point description:

Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration, from Day 1, is calculated with exact 95% CI by ELISA.

End point type	Primary

End point timeframe:

At Day 29, compared to pre-vaccination at Day 1

Notes:

[32] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	41	40
Units: Percentage of subjects				
number (confidence interval 95%)	58.1 (42.1 to 73.0)	35 (20.6 to 51.7)	61 (44.5 to 75.8)	30 (16.6 to 46.5)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	37	41
Units: Percentage of subjects				
number (confidence interval 95%)	21.4 (10.3 to 36.8)	42.9 (27.7 to 59.0)	13.5 (4.5 to 28.8)	2.4 (0.1 to 12.9)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Percentage of subjects				
number (confidence interval 95%)	15.4 (5.9 to 30.5)	2.5 (0.1 to 13.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration measured by ELISA – Day 85

End point title	Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration measured by ELISA – Day 85[33]

End point description:

Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration, from Day 1, is calculated with exact 95% CI by ELISA.

End point type	Primary

End point timeframe:

At Day 85, compared to pre-vaccination at Day 1

Notes:

[33] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	36	34	35
Units: Percentage of subjects				
number (confidence interval 95%)	12.8 (4.3 to 27.4)	5.6 (0.7 to 18.7)	47.1 (29.8 to 64.9)	17.1 (6.6 to 33.6)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	35	34	34
Units: Percentage of subjects				
number (confidence interval 95%)	5.1 (0.6 to 17.3)	25.7 (12.5 to 43.3)	17.6 (6.8 to 34.5)	2.9 (0.1 to 15.3)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	38		
Units: Percentage of subjects				
number (confidence interval 95%)	14.3 (4.8 to 30.3)	5.3 (0.6 to 17.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk titer measured by MN assay – Day 29

End point title	Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk titer measured by MN assay – Day 29[34]

End point description:

Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody titer from Day 1, is calculated with exact 95% CI by MN assay.

End point type	Primary

End point timeframe:

At Day 29, compared to pre-vaccination at Day 1

Notes:

[34] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	38	38	39
Units: Percentage of subjects				
number (confidence interval 95%)	7.1 (1.5 to 19.5)	7.9 (1.7 to 21.4)	10.5 (2.9 to 24.8)	5.1 (0.6 to 17.3)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	41	35	38
Units: Percentage of subjects				
number (confidence interval 95%)	7.9 (1.7 to 21.4)	4.9 (0.6 to 16.5)	8.6 (1.8 to 23.1)	2.6 (0.1 to 13.8)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	36		
Units: Percentage of subjects				
number (confidence interval 95%)	2.7 (0.1 to 14.2)	2.8 (0.1 to 14.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk titer measured by MN assay – Day 85

End point title	Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk titer measured by MN assay – Day 85[35]

End point description:

Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody titer from Day 1, is calculated with exact 95% CI by MN assay.

End point type	Primary

End point timeframe:

At Day 85, compared to pre-vaccination at Day 1

Notes:

[35] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	34	32	33
Units: Percentage of subjects				
number (confidence interval 95%)	2.7 (0.1 to 14.2)	8.8 (1.9 to 23.7)	15.6 (5.3 to 32.8)	3 (0.1 to 15.8)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	34	33	32
Units: Percentage of subjects				
number (confidence interval 95%)	8.6 (1.8 to 23.1)	8.8 (1.9 to 23.7)	0 (0.0 to 10.6)	6.3 (0.8 to 20.8)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: Percentage of subjects				
number (confidence interval 95%)	3 (0.1 to 15.8)	2.9 (0.1 to 15.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Mean Geometric Increase (MGI) for anti-H1 stalk antibody concentration measured by ELISA – Day 29

End point title	Mean Geometric Increase (MGI) for anti-H1 stalk antibody concentration measured by ELISA – Day 29[36]

End point description:

MGI is defined as the geometric mean of the fold increase in serum HI concentration post-vaccination compared to Day 1

End point type	Primary

End point timeframe:

At Day 29, compared to pre-vaccination at Day 1

Notes:

[36] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	41	40
Units: Ratio				
geometric mean (confidence interval 95%)	12.4 (9.2 to 16.7)	5.9 (4.4 to 8.0)	12.6 (9.2 to 17.1)	6.8 (4.9 to 9.5)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	37	41
Units: Ratio				
geometric mean (confidence interval 95%)	4.7 (3.6 to 6.2)	8.1 (6.2 to 10.5)	4.2 (2.9 to 6.2)	2.3 (1.8 to 3.0)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Ratio				
geometric mean (confidence interval 95%)	3.9 (2.8 to 5.4)	2.4 (1.9 to 2.9)		

Statistical analyses

No statistical analyses for this end point

Primary: MGI for anti-H1 stalk antibody concentration measured by ELISA – Day 85

End point title	MGI for anti-H1 stalk antibody concentration measured by ELISA – Day 85[37]

End point description:

MGI is defined as the geometric mean of the fold increase in serum HI concentration post-vaccination compared to Day 1

End point type	Primary

End point timeframe:

At Day 85, compared to pre-vaccination at Day 1

Notes:

[37] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	36	34	35
Units: Ratio				
geometric mean (confidence interval 95%)	5 (3.9 to 6.5)	3.4 (2.6 to 4.5)	8.1 (6.1 to 10.8)	3.4 (2.4 to 4.9)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	35	34	34
Units: Ratio				
geometric mean (confidence interval 95%)	2.6 (2.1 to 3.2)	6.3 (5.0 to 7.9)	3.4 (2.3 to 5.0)	1.7 (1.4 to 2.1)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	38		
Units: Ratio				
geometric mean (confidence interval 95%)	3.8 (2.7 to 5.5)	1.8 (1.5 to 2.3)		

Statistical analyses

No statistical analyses for this end point

Primary: MGI for anti-H1 stalk antibody titer measured by MN assay – Day 29

End point title	MGI for anti-H1 stalk antibody titer measured by MN assay – Day 29[38]

End point description:

MGI is defined as the geometric mean of the fold increase in serum HI titer post-vaccination compared to Day 1

End point type	Primary

End point timeframe:

At Day 29, compared to pre-vaccination at Day 1

Notes:

[38] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	38	38	39
Units: Ratio				
geometric mean (confidence interval 95%)	2.4 (1.7 to 3.3)	2.6 (1.9 to 3.6)	2.4 (1.8 to 3.3)	2.3 (1.7 to 3.2)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	41	35	38
Units: Ratio				
geometric mean (confidence interval 95%)	2.3 (1.7 to 3.2)	2 (1.5 to 2.7)	2.3 (1.7 to 3.2)	1.9 (1.4 to 2.5)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	36		
Units: Ratio				
geometric mean (confidence interval 95%)	1.7 (1.2 to 2.4)	2.2 (1.6 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Primary: MGI for anti-H1 stalk antibody titer measured by MN assay – Day 85

End point title	MGI for anti-H1 stalk antibody titer measured by MN assay – Day 85[39]

End point description:

MGI is defined as the geometric mean of the fold increase in serum HI titer post-vaccination compared to Day 1

End point type	Primary

End point timeframe:

At Day 85, compared to pre-vaccination at Day 1

Notes:

[39] - 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: This outcome was descriptive; hence no statistical analyses were required.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	34	32	33
Units: Ratio				
geometric mean (confidence interval 95%)	1.6 (1.2 to 2.2)	2.2 (1.5 to 3.2)	2.5 (1.7 to 3.7)	1.1 (0.8 to 1.6)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	34	33	32
Units: Ratio				
geometric mean (confidence interval 95%)	2 (1.5 to 2.8)	2.5 (1.7 to 3.5)	1.2 (0.9 to 1.7)	1.6 (1.1 to 2.2)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: Ratio				
geometric mean (confidence interval 95%)	2 (1.4 to 2.8)	2.4 (1.7 to 3.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted GMCs for anti-H1 HA stalk antibody measured by ELISA

End point title	Adjusted GMCs for anti-H1 HA stalk antibody measured by ELISA

End point description:

The adjusted GMCs are presented to evaluate the adjuvant effect post-dose 1 and post-dose 2.

End point type	Secondary

End point timeframe:

28 days post priming dose(s) i.e. at Day 29 for 1 priming dose groups and at Day 85 for 2 priming doses groups

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	34	40
Units: EL.U/mL				
geometric mean (confidence interval 95%)	112206.4 (91362.2 to 137806.3)	47432.6 (38317.4 to 58716.2)	73945.6 (58686.6 to 93172.2)	61356.7 (49582.3 to 75927)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	35	37	41
Units: EL.U/mL				
geometric mean (confidence interval 95%)	45346.6 (36827 to 55837.2)	50602.8 (40283.4 to 63565.8)	36159.3 (28972.3 to 45129)	20403.5 (16531.4 to 25182.7)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	40		
Units: EL.U/mL				
geometric mean (confidence interval 95%)	36826.9 (29320 to 46255.8)	21675.2 (17515.2 to 26823.1)		

Statistical analyses

Statistical analysis title	AS03 adjuvant effect for anti-H1 stalk

Statistical analysis description:

To evaluate the adjuvant effect of AS03 (Pooling of results at Day 29 of D-SUIV Adjuvant Group 1, at Day 29 of D-SUIV Adjuvant Group 2 and Day 85 of D-SUIV Adjuvant Group 3) on the humoral immune response for anti-H1 stalk antibody by ELISA at Day 29 and Day 85 (i.e. 28 days post-vaccination) when compared to the non-adjuvanted formulations (Pooling of results at Day 29 of D-SUIV Unadjuvanted Group 1, at Day 29 of D-SUIV Unadjuvanted Group 2 and Day 85 of D-SUIV Unadjuvanted Group 3).

Comparison groups	D-SUIV Adjuvanted Group 1 v D-SUIV Unadjuvanted Group 1

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
Method	Dunnett’s t test
Parameter estimate	GMC ratio
Point estimate	2.47
Confidence interval	
level	Other: 94.46 %
sides	2-sided
lower limit	2.06
upper limit	2.95

Statistical analysis title	AS01 Adjuvant effect for Anti-H1 stalk

Statistical analysis description:

To evaluate the adjuvant effect of AS01 (Pooling of results at Day 29 of D-SUIV Adjuvant Group 4, at Day 29 of D-SUIV Adjuvant Group 5 and Day 85 of D-SUIV Adjuvant Group 6) on the humoral immune response for anti-H1 stalk antibody by ELISA at Day 29 and Day 85 (i.e. 28 days post-vaccination) when compared to the non-adjuvanted formulations (Pooling of results at Day 29 of D-SUIV Unadjuvanted Group 1, at Day 29 of D-SUIV Unadjuvanted Group 2 and Day 85 of D-SUIV Unadjuvanted Group 3).

Comparison groups	D-SUIV Adjuvanted Group 4 v D-SUIV Unadjuvanted Group 1
Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	
Method	Dunnett’s t test
Parameter estimate	GMC ratio
Point estimate	1.75
Confidence interval	
level	Other: 94.46 %
sides	2-sided
lower limit	1.46
upper limit	2.1

Secondary: Concentrations of serum H1 stalk antibodies measured by ELISA– Month 8 to 26

End point title	Concentrations of serum H1 stalk antibodies measured by ELISA– Month 8 to 26

End point description:

Concentrations are presented as GMCs and measured by ELISA. ELISA cut-off = 66 EL.U/mL.

End point type	Secondary

End point timeframe:

At Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	34	30	27
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	27068.3 (21884.3 to 33480.4)	17155.9 (13158.7 to 22367.4)	41759.7 (32814.0 to 53144.1)	18915.3 (15026.4 to 23810.7)
M14 (N=35;32;26;26;31;31;25;30;30;31)	22687.1 (18078.5 to 28470.4)	17662.4 (14339.6 to 21755.1)	37282.2 (29437.7 to 47216.9)	20146.8 (15305.9 to 26518.8)
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	49594 (39888.4 to 61661.1)	92885.6 (73985.7 to 116613.7)	73078 (62288.9 to 85736.0)	36709.7 (30186.1 to 44643.2)
M20 (N=29;30;24;24;31;27;20;27;27;25)	27648.6 (22712.3 to 33657.7)	36133.6 (29063.7 to 44923.2)	38120.3 (30433.7 to 47748.2)	21916.1 (17219.1 to 27894.4)
M26 (N=29;29;22;21;25;25;20;25;25;23)	22850.2 (18790.0 to 27787.8)	29027.2 (23343.2 to 36095.3)	32635.4 (26013.9 to 40942.3)	18266 (14093.9 to 23673.1)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	33	30	34
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	15092.4 (12226.1 to 18630.8)	25279.1 (20711.4 to 30854.2)	19028.4 (13706.8 to 26416.0)	11024.8 (8751.5 to 13888.6)
M14 (N=35;32;26;26;31;31;25;30;30;31)	16645.4 (12389.7 to 22362.8)	24615 (19677.5 to 30791.4)	16969.8 (11848.5 to 24304.6)	10820.3 (8524.9 to 13733.9)
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	75155.7 (56729.2 to 99567.4)	52026.4 (42254.7 to 64057.8)	22653.6 (16071.5 to 31931.4)	29508.2 (21062.2 to 41341.1)
M20 (N=29;30;24;24;31;27;20;27;27;25)	31396.4 (24953.9 to 39502.2)	29988.8 (24033.9 to 37419.1)	18408.1 (12608.3 to 26875.7)	16632.9 (12484.8 to 22159.2)
M26 (N=29;29;22;21;25;25;20;25;25;23)	27491.3 (20448.3 to 36960.2)	25059.4 (19893.4 to 31567.0)	18220.9 (12067.9 to 27511.0)	14269 (10104.9 to 20149.0)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: EL.U/mL				
geometric mean (confidence interval				

95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	22359.8 (18089.1 to 27638.8)	13142.1 (10306.0 to 16758.7)		
M14 (N=35;32;26;26;31;31;25;30;30;31)	22791.5 (17767.3 to 29236.4)	12458.4 (9721.6 to 15965.7)		
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	38364 (30403.9 to 48408.1)	17593.3 (13932.1 to 22216.6)		
M20 (N=29;30;24;24;31;27;20;27;27;25)	23145.3 (18447.2 to 29039.9)	12635.2 (9489.2 to 16824.1)		
M26 (N=29;29;22;21;25;25;20;25;25;23)	21673.7 (17482.9 to 26869.2)	12050.6 (8943.4 to 16237.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-H1 stalk antibodies measured by ELISA– Month 8 to 26

End point title	Number of seropositive subjects for anti-H1 stalk antibodies measured by ELISA– Month 8 to 26

End point description:

Anti-H1 stalk immune response measured by ELISA. A seropositive subject is a subject whose concentration is greater than or equal to the cut-off value: ELISA cut-off = 66 EL.U/mL.

End point type	Secondary

End point timeframe:

At Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26.

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	34	30	27
Units: Participants				
M8 (N=39;34;30;27;36;33;30;34;33;34)	39	34	30	27
M14 (N=35;32;26;26;31;31;25;30;30;31)	35	32	26	26
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	28	31	23	25
M20 (N=29;30;24;24;31;27;20;27;27;25)	29	30	24	24
M26 (N=29;29;22;21;25;25;20;25;25;23)	29	29	22	21

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	33	30	34
Units: Participants				
M8 (N=39;34;30;27;36;33;30;34;33;34)	36	33	30	34
M14 (N=35;32;26;26;31;31;25;30;30;31)	31	31	25	30
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	29	29	22	26
M20 (N=29;30;24;24;31;27;20;27;27;25)	31	27	20	27
M26 (N=29;29;22;21;25;25;20;25;25;23)	25	25	20	25

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: Participants				
M8 (N=39;34;30;27;36;33;30;34;33;34)	33	34		
M14 (N=35;32;26;26;31;31;25;30;30;31)	30	31		
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	27	29		
M20 (N=29;30;24;24;31;27;20;27;27;25)	27	25		
M26 (N=29;29;22;21;25;25;20;25;25;23)	25	23		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody concentration, measured by ELISA – Month 8 to 26.

End point title	Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody concentration, measured by ELISA – Month 8 to 26.

End point description:

Percentage of subjects with a ≥ 4-fold increase of anti-H1 stalk antibody concentration, from Day 1, is calculated with exact 95% CI by ELISA.

End point type	Secondary

End point timeframe:

At Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	34	30	27
Units: Percentage of subjects				
number (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	23.1 (11.1 to 39.3)	23.5 (10.7 to 41.2)	53.3 (34.3 to 71.7)	14.8 (4.2 to 33.7)
M14 (N=35;32;26;26;31;31;25;30;30;31)	20 (8.4 to 36.9)	25 (11.5 to 43.4)	50 (29.9 to 70.1)	30.8 (14.3 to 51.8)
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	46.4 (27.5 to 66.1)	83.9 (66.3 to 94.5)	82.6 (61.2 to 95.0)	44 (24.4 to 65.1)
M20 (N=29;30;24;24;31;27;20;27;27;25)	27.6 (12.7 to 47.2)	60 (40.6 to 77.3)	50 (29.1 to 70.9)	33.3 (15.6 to 55.3)
M26 (N=29;29;22;21;25;25;20;25;25;23)	20.7 (8.0 to 39.7)	41.4 (23.5 to 61.1)	36.4 (17.2 to 59.3)	28.6 (11.3 to 52.2)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	33	30	34
Units: Percentage of subjects				
number (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	5.6 (0.7 to 18.7)	39.4 (22.9 to 57.9)	23.3 (9.9 to 42.3)	8.8 (1.9 to 23.7)
M14 (N=35;32;26;26;31;31;25;30;30;31)	9.7 (2.0 to 25.8)	38.7 (21.8 to 57.8)	12 (2.5 to 31.2)	3.3 (0.1 to 17.2)
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	69 (49.2 to 84.7)	75.9 (56.5 to 89.7)	22.7 (7.8 to 45.4)	38.5 (20.2 to 59.4)
M20 (N=29;30;24;24;31;27;20;27;27;25)	38.7 (21.8 to 57.8)	48.1 (28.7 to 68.1)	20 (5.7 to 43.7)	11.1 (2.4 to 29.2)
M26 (N=29;29;22;21;25;25;20;25;25;23)	32 (14.9 to 53.5)	36 (18.0 to 57.5)	15 (3.2 to 37.9)	8 (1.0 to 26.0)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: Percentage of subjects				
number (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	21.2 (9.0 to 38.9)	0 (0.0 to 10.3)		
M14 (N=35;32;26;26;31;31;25;30;30;31)	13.3 (3.8 to 30.7)	0 (0.0 to 11.2)		
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	33.3 (16.5 to 54.0)	10.3 (2.2 to 27.4)		
M20 (N=29;30;24;24;31;27;20;27;27;25)	25.9 (11.1 to 46.3)	0 (0.0 to 13.7)		
M26 (N=29;29;22;21;25;25;20;25;25;23)	24 (9.4 to 45.1)	0 (0.0 to 14.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration, measured by ELISA – Month 8 to 26.

End point title	Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration, measured by ELISA – Month 8 to 26.

End point description:

Percentage of subjects with a ≥ 10-fold increase of anti-H1 stalk antibody concentration, from Day 1, is calculated with exact 95% CI by ELISA.

End point type	Secondary

End point timeframe:

At Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	34	30	27
Units: Percentage of subjects				
number (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	7.7 (1.6 to 20.9)	0 (0.0 to 10.3)	23.3 (9.9 to 42.3)	7.4 (0.9 to 24.3)
M14 (N=35;32;26;26;31;31;25;30;30;31)	5.7 (0.7 to 19.2)	3.1 (0.1 to 16.2)	30.8 (14.3 to 51.8)	3.8 (0.1 to 19.6)
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	17.9 (6.1 to 36.9)	58.1 (39.1 to 75.5)	52.2 (30.6 to 73.2)	24 (9.4 to 45.1)
M20 (N=29;30;24;24;31;27;20;27;27;25)	10.3 (2.2 to 27.4)	26.7 (12.3 to 45.9)	16.7 (4.7 to 37.4)	8.3 (1.0 to 27.0)
M26 (N=29;29;22;21;25;25;20;25;25;23)	3.4 (0.1 to 17.8)	13.8 (3.9 to 31.7)	4.5 (0.1 to 22.8)	4.8 (0.1 to 23.8)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	33	30	34
Units: Percentage of subjects				
number (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	0 (0.0 to 9.7)	9.1 (1.9 to 24.3)	10 (2.1 to 26.5)	0 (0.0 to 10.3)

M14 (N=35;32;26;26;31;31;25;30;30;31)	3.2 (0.1 to 16.7)	3.2 (0.1 to 16.7)	4 (0.1 to 20.4)	0 (0.0 to 11.6)
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	37.9 (20.7 to 57.7)	34.5 (17.9 to 54.3)	4.5 (0.1 to 22.8)	11.5 (2.4 to 30.2)
M20 (N=29;30;24;24;31;27;20;27;27;25)	9.7 (2.0 to 25.8)	11.1 (2.4 to 29.2)	5 (0.1 to 24.9)	3.7 (0.1 to 19.0)
M26 (N=29;29;22;21;25;25;20;25;25;23)	4 (0.1 to 20.4)	12 (2.5 to 31.2)	10 (1.2 to 31.7)	4 (0.1 to 20.4)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: Percentage of subjects				
number (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	9.1 (1.9 to 24.3)	0 (0.0 to 10.3)		
M14 (N=35;32;26;26;31;31;25;30;30;31)	10 (2.1 to 26.5)	0 (0.0 to 11.2)		
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	18.5 (6.3 to 38.1)	0 (0.0 to 11.9)		
M20 (N=29;30;24;24;31;27;20;27;27;25)	11.1 (2.4 to 29.2)	0 (0.0 to 13.7)		
M26 (N=29;29;22;21;25;25;20;25;25;23)	12 (2.5 to 31.2)	0 (0.0 to 14.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: MGI for anti-H1 stalk antibody measured by ELISA – Month 8 to 26

End point title	MGI for anti-H1 stalk antibody measured by ELISA – Month 8 to 26

End point description:

MGI is defined as the geometric mean of the fold increase in serum HI concentration post-vaccination compared to Day 1

End point type	Secondary

End point timeframe:

At Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	34	30	27
Units: Ratio				
geometric mean (confidence interval 95%)				

M8 (N=39;34;30;27;36;33;30;34;33;34)	2.9 (2.2 to 3.7)	2.3 (1.8 to 2.9)	4.7 (3.5 to 6.3)	2 (1.4 to 2.8)
M14 (N=35;32;26;26;31;31;25;30;30;31)	2.5 (2.0 to 3.2)	2.4 (1.8 to 3.2)	4.7 (3.2 to 6.8)	2.3 (1.7 to 3.2)
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	5.3 (3.7 to 7.7)	12.6 (8.7 to 18.2)	9.5 (6.6 to 13.6)	4.3 (3.0 to 6.4)
M20 (N=29;30;24;24;31;27;20;27;27;25)	3 (2.3 to 3.8)	4.9 (3.5 to 6.8)	4.6 (3.3 to 6.3)	2.6 (1.8 to 3.8)
M26 (N=29;29;22;21;25;25;20;25;25;23)	2.7 (2.0 to 3.5)	3.7 (2.7 to 5.2)	3.7 (2.7 to 5.2)	2.3 (1.5 to 3.6)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	33	30	34
Units: Ratio				
geometric mean (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	1.4 (1.2 to 1.8)	3.3 (2.6 to 4.3)	2.2 (1.5 to 3.1)	1.3 (1.1 to 1.7)
M14 (N=35;32;26;26;31;31;25;30;30;31)	1.6 (1.2 to 2.1)	3.2 (2.5 to 4.2)	2 (1.4 to 2.8)	1.2 (1.0 to 1.5)
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	7.3 (5.0 to 10.7)	7.1 (5.3 to 9.5)	2.7 (2.0 to 3.8)	3.4 (2.3 to 5.0)
M20 (N=29;30;24;24;31;27;20;27;27;25)	3.1 (2.3 to 4.1)	4 (3.0 to 5.3)	2.2 (1.5 to 3.2)	1.8 (1.4 to 2.3)
M26 (N=29;29;22;21;25;25;20;25;25;23)	2.6 (1.9 to 3.7)	3.3 (2.4 to 4.4)	2.1 (1.4 to 3.3)	1.5 (1.1 to 2.1)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: Ratio				
geometric mean (confidence interval 95%)				
M8 (N=39;34;30;27;36;33;30;34;33;34)	2.4 (1.7 to 3.3)	1.3 (1.1 to 1.5)		
M14 (N=35;32;26;26;31;31;25;30;30;31)	2.1 (1.4 to 3.1)	1.2 (1.0 to 1.4)		
M14+28 days (N=28;31;23;25;29;29;22;26;27;29)	4.1 (2.6 to 6.3)	1.7 (1.3 to 2.2)		
M20 (N=29;30;24;24;31;27;20;27;27;25)	2.5 (1.7 to 3.6)	1.3 (1.1 to 1.6)		
M26 (N=29;29;22;21;25;25;20;25;25;23)	2.2 (1.5 to 3.3)	1.3 (1.1 to 1.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-H2 and anti-H18 antibodies measured by ELISA

End point title	Concentrations of anti-H2 and anti-H18 antibodies measured by ELISA

End point description:

Concentrations are presented as GMCs and measured by ELISA. ELISA cut-off = 22 EL.U/mL (H2) and 43 EL.U/mL (H18).

End point type	Secondary

End point timeframe:

At Days 1, 29, 85, Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	47	47
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-H2, Day 1 (N=45;46;47;47;48;47;47;46;44;45)	5848.2 (4577.0 to 7472.5)	5975.5 (4615.6 to 7736.1)	6882.1 (5488.8 to 8629.2)	5968.7 (4723.0 to 7542.9)
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	111973.1 (90350.2 to 138770.8)	28538 (22181.5 to 36716.0)	115020.5 (93922.9 to 140857.1)	59190.1 (46420.7 to 75472.2)
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	42295.4 (34505.4 to 51844.2)	18172.7 (13948.3 to 23676.6)	60609.1 (47899.9 to 76690.5)	26581.4 (19839.5 to 35614.4)
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	29904.9 (24015.3 to 37238.9)	12923.2 (9816.8 to 17012.6)	38258.4 (29536.3 to 49556.3)	18259.9 (13789.8 to 24179.0)
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	21754.4 (17375.9 to 27236.2)	11417.4 (8969.1 to 14534.0)	30670.3 (23748.7 to 39609.2)	17100.4 (12454.3 to 23479.8)
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26;27;29)	36459.1 (29419.5 to 45183.3)	91778 (73053.9 to 115301.3)	76909.5 (63594.4 to 93012.4)	27256.3 (20573.9 to 36109.3)
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	24198.7 (19291.6 to 30353.9)	34266 (26622.0 to 44104.8)	36950 (29306.1 to 46587.6)	19456.7 (14167.4 to 26720.7)
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	20136.5 (16257.6 to 24940.8)	27000.7 (21059.5 to 34617.9)	29403.8 (22530.7 to 38373.5)	15358.6 (11070.7 to 21307.3)
Anti-H18, Day 1 (N=45;46;46;47;48;47;47;46;44;45)	4936.1 (3878.3 to 6282.3)	4845.1 (3641.3 to 6446.9)	5936.9 (4557.4 to 7734.1)	5299.3 (4197.0 to 6691.1)
Anti-H18, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	26663.7 (21555.9 to 32981.8)	19762.5 (15199.9 to 25694.6)	30387.7 (25266.3 to 36547.2)	19951 (16410.4 to 24255.6)
Anti-H18, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	13071 (10618.2 to 16090.3)	13472.1 (10474.3 to 17327.9)	27305.6 (22369.5 to 33330.8)	10270.7 (8541.1 to 12350.5)
Anti-H18, M8 (N=39;34;30;27;36;33;30;34;33;34)	11992.9 (9665.8 to 14880.2)	10240.6 (7932.7 to 13220.0)	18529.9 (15273.7 to 22480.4)	10260.8 (8094.5 to 13006.8)

Anti-H18, M14 (N=35;32;26;26;31;31;25;30;30;31)	9039.6 (7212.3 to 11329.9)	8610.3 (6938.0 to 10685.6)	14078.6 (11455.9 to 17301.7)	8820.4 (6959.4 to 11179.1)
Anti-H18, M14+28d(N=28;31;23;25;29;29;22;26;27;29)	19763.3 (15225.3 to 25653.9)	26567.6 (21331.9 to 33088.4)	20291 (17142.5 to 24017.8)	15768 (12672.2 to 19620.0)
Anti-H18, M20 (N=29;30;24;24;31;27;20;27;27;25)	12192 (9446.1 to 15736.1)	14228.2 (11276.5 to 17952.5)	13068.8 (10894.9 to 15676.5)	10503.1 (8169.3 to 13503.6)
Anti-H18, M26 (N=29;29;22;21;25;25;20;25;25;23)	10832.8 (8488.3 to 13825.0)	11823.4 (9575.2 to 14599.4)	12186.4 (9948.2 to 14928.2)	9767.9 (7407.6 to 12880.1)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	47	46
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-H2, Day 1 (N=45;46;47;47;48;47;47;46;44;45)	6704 (5329.0 to 8433.8)	5513.6 (4551.7 to 6678.7)	6042.3 (4790.1 to 7622.0)	5917.2 (4681.7 to 7478.9)
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	30980 (25025.9 to 38350.8)	64182.7 (50875.4 to 80970.8)	30976.4 (20643.7 to 46481.0)	12700 (10182.5 to 15839.8)
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	16519.5 (13127.6 to 20787.9)	39576.4 (31245.9 to 50128.0)	23576.8 (15654.3 to 35508.7)	9640.8 (7382.5 to 12590.1)
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	12402.4 (9535.4 to 16131.4)	24555.6 (19235.1 to 31347.7)	19264.5 (13044.6 to 28450.1)	8229 (6456.6 to 10488.1)
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	10899.7 (8122.1 to 14627.2)	19573.6 (14935.3 to 25652.3)	15050.2 (9969.1 to 22721.0)	7717.7 (5839.8 to 10199.6)
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26;27;29)	81616.2 (64374.2 to 103476.4)	58542.1 (47219.6 to 72579.5)	19172.9 (12543.2 to 29306.6)	29940.3 (20765.3 to 43169.3)
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	32287.4 (25257.3 to 41274.2)	28818 (22130.7 to 37525.9)	14269 (9295.0 to 21905.0)	15780.8 (11287.6 to 22062.7)
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	27477.2 (20295.7 to 37199.7)	22917.6 (17205.8 to 30525.6)	14906.4 (9433.3 to 23554.9)	13186.7 (9162.6 to 18978.2)
Anti-H18, Day 1 (N=45;46;46;47;48;47;47;46;44;45)	5368.1 (4259.0 to 6766.0)	4651.7 (3734.8 to 5793.7)	4991.2 (4039.5 to 6167.0)	5543.3 (4394.6 to 6992.4)
Anti-H18, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	21416.3 (17539.0 to 26150.8)	19348 (16009.2 to 23383.0)	13383.5 (9734.9 to 18399.5)	10899.9 (8829.7 to 13455.5)
Anti-H18, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	12017.1 (9474.7 to 15241.8)	17205.7 (14796.1 to 20007.7)	10062.6 (7439.9 to 13610.1)	8762.3 (6910.2 to 11110.9)
Anti-H18, M8 (N=39;34;30;27;36;33;30;34;33;34)	9973.8 (7709.1 to 12903.9)	12753.8 (10434.4 to 15588.8)	9988.8 (7297.7 to 13672.3)	8182.1 (6517.6 to 10271.7)
Anti-H18, M14 (N=35;32;26;26;31;31;25;30;30;31)	8370.2 (6213.2 to 11276.0)	10216.5 (8035.8 to 12989.1)	8526.2 (6047.8 to 12020.2)	6955.8 (5553.1 to 8713.0)

Anti-H18, M14+28d(N=28;31;23;25;29;29;22;26;27;29)	24020.6 (19157.0 to 30118.9)	15872.3 (12888.2 to 19547.3)	11742.6 (8553.4 to 16120.9)	12543.5 (9593.4 to 16400.7)
Anti-H18, M20 (N=29;30;24;24;31;27;20;27;27;25)	12541.2 (9836.1 to 15990.2)	10695.2 (8464.7 to 13513.5)	9695.4 (6545.1 to 14362.2)	8934.7 (6832.5 to 11683.6)
Anti-H18, M26 (N=29;29;22;21;25;25;20;25;25;23)	11445.8 (8371.9 to 15648.3)	9308.8 (7285.1 to 11894.6)	10283.6 (6627.6 to 15956.4)	7937 (5903.9 to 10670.1)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	45		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-H2, Day 1 (N=45;46;47;47;48;47;47;46;44;45)	6320.1 (4858.6 to 8221.2)	5512.2 (4373.1 to 6948.0)		
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	33198.1 (25465.3 to 43279.1)	10941.3 (8962.2 to 13357.5)		
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	29437.8 (22555.8 to 38419.7)	8939.2 (7063.2 to 11313.4)		
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	22379.6 (17763.5 to 28195.2)	9409 (7202.0 to 12292.4)		
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	21978.5 (17171.0 to 28132.1)	8582.5 (6443.9 to 11430.8)		
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26;27;29)	41953 (34398.2 to 51167.0)	11753.1 (9023.9 to 15307.8)		
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	25006.7 (19478.3 to 32104.2)	7961.8 (5712.7 to 11096.2)		
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	23570.6 (18496.4 to 30036.9)	7708.3 (5593.3 to 10623.1)		
Anti-H18, Day 1 (N=45;46;46;47;48;47;47;46;44;45)	5399.2 (4075.9 to 7152.3)	5681.1 (4327.4 to 7458.4)		
Anti-H18, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	14152.1 (11530.1 to 17370.3)	11675.5 (9209.8 to 14801.4)		
Anti-H18, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	15219.4 (12301.2 to 18829.9)	9136.2 (6966.1 to 11982.3)		
Anti-H18, M8 (N=39;34;30;27;36;33;30;34;33;34)	12617.3 (10198.5 to 15609.8)	9590.3 (7160.5 to 12844.6)		
Anti-H18, M14 (N=35;32;26;26;31;31;25;30;30;31)	11876.7 (9622.1 to 14659.6)	8178.4 (6007.8 to 11133.2)		
Anti-H18, M14+28d(N=28;31;23;25;29;29;22;26;27;29)	14564 (12163.0 to 17439.0)	10758.1 (8190.4 to 14130.7)		

Anti-H18, M20 (N=29;30;24;24;31;27;20;27;27;25)	12302.2 (9853.6 to 15359.2)	7764.5 (5518.3 to 10925.1)		
Anti-H18, M26 (N=29;29;22;21;25;25;20;25;25;23)	11617.9 (8948.6 to 15083.3)	7646.4 (5326.5 to 10976.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-H2 and anti-H18 antibodies measured by ELISA

End point title	Number of seropositive subjects for anti-H2 and anti-H18 antibodies measured by ELISA

End point description:

Anti-H2 and anti-H18 immune response measured by ELISA. A seropositive subject is a subject whose concentration is greater than or equal to the cut-off value: ELISA cut-off = 22 EL.U/mL (H2) and 43 EL.U/mL (H18).

End point type	Secondary

End point timeframe:

At Days 1, 29, 85, Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	47	47
Units: Participants				
Anti-H2, Day 1 (N=45;46;47;47;48;47;47;46;44;45)	45	46	47	47
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	43	40	41	40
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	39	36	34	35
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	39	34	30	27
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	35	32	26	26
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	28	31	23	25
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	29	30	24	24
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	29	29	22	21
Anti-H18, Day 1 (N=45;46;46;47;48;47;47;46;44;45)	45	46	46	47
Anti-H18, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	43	40	41	40
Anti-H18, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	39	36	34	35
Anti-H18, M8 (N=39;34;30;27;36;33;30;34;33;34)	39	34	30	27

Anti-H18, M14 (N=35;32;26;26;31;31;25;30;30;31)	35	32	26	26
Anti-H18, M14+28d(N=28;31;23;25;29;29;22;26	28	31	23	25
Anti-H18, M20 (N=29;30;24;24;31;27;20;27;27;25)	29	30	24	24
Anti-H18, M26 (N=29;29;22;21;25;25;20;25;25;23)	29	29	22	21

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	47	46
Units: Participants				
Anti-H2, Day 1 (N=45;46;47;47;48;47;47;46;44;45)	48	47	47	46
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	42	42	37	41
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	39	35	34	34
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	36	33	30	34
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	31	31	25	30
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	29	29	22	26
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	31	27	20	27
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	25	25	20	25
Anti-H18, Day 1 (N=45;46;46;47;48;47;47;46;44;45)	48	47	47	46
Anti-H18, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	42	42	37	41
Anti-H18, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	39	35	34	34
Anti-H18, M8 (N=39;34;30;27;36;33;30;34;33;34)	36	33	30	34
Anti-H18, M14 (N=35;32;26;26;31;31;25;30;30;31)	31	31	25	30
Anti-H18, M14+28d(N=28;31;23;25;29;29;22;26	29	29	22	26
Anti-H18, M20 (N=29;30;24;24;31;27;20;27;27;25)	31	27	20	27
Anti-H18, M26 (N=29;29;22;21;25;25;20;25;25;23)	25	25	20	25

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	45		
Units: Participants				

Anti-H2, Day 1 (N=45;46;47;47;48;47;47;46;44;45)	44	45		
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	39	40		
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	35	38		
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	33	34		
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	30	31		
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	27	29		
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	27	25		
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	25	23		
Anti-H18, Day 1 (N=45;46;46;47;48;47;47;46;44;45)	44	45		
Anti-H18, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	39	40		
Anti-H18, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	35	38		
Anti-H18, M8 (N=39;34;30;27;36;33;30;34;33;34)	33	34		
Anti-H18, M14 (N=35;32;26;26;31;31;25;30;30;31)	30	31		
Anti-H18, M14+28d(N=28;31;23;25;29;29;22;26	27	29		
Anti-H18, M20 (N=29;30;24;24;31;27;20;27;27;25)	27	25		
Anti-H18, M26 (N=29;29;22;21;25;25;20;25;25;23)	25	23		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with a ≥ 4-fold increase of anti-H2 and anti-H18 antibody concentration measured by ELISA

End point title	Percentage of subjects with a ≥ 4-fold increase of anti-H2 and anti-H18 antibody concentration measured by ELISA

End point description:

Percentage of subjects with a ≥ 4-fold increase of anti-H2 and anti-H18 antibody concentration, from Day 1, is calculated with exact 95% CI by ELISA .

End point type	Secondary

End point timeframe:

At Day 29, at Day 85, Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	41	40
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	95.3 (84.2 to 99.4)	62.5 (45.8 to 77.3)	92.7 (80.1 to 98.5)	82.5 (67.2 to 92.7)
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	66.7 (49.8 to 80.9)	36.1 (20.8 to 53.8)	79.4 (62.1 to 91.3)	45.7 (28.8 to 63.4)
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	51.3 (34.8 to 67.6)	23.5 (10.7 to 41.2)	73.3 (54.1 to 87.7)	29.6 (13.8 to 50.2)
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	34.3 (19.1 to 52.2)	15.6 (5.3 to 32.8)	61.5 (40.6 to 79.8)	30.8 (14.3 to 51.8)
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	57.1 (37.2 to 75.5)	100 (88.8 to 100.0)	100 (85.2 to 100.0)	52 (31.3 to 72.2)
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	41.4 (23.5 to 61.1)	70 (50.6 to 85.3)	75 (53.3 to 90.2)	41.7 (22.1 to 63.4)
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	41.4 (23.5 to 61.1)	62.1 (42.3 to 79.3)	54.5 (32.2 to 75.6)	38.1 (18.1 to 61.6)
Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	55.8 (39.9 to 70.9)	52.5 (36.1 to 68.5)	50 (33.8 to 66.2)	40 (24.9 to 56.7)
Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	17.9 (7.5 to 33.5)	33.3 (18.6 to 51.0)	48.5 (30.8 to 66.5)	14.3 (4.8 to 30.3)
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	12.8 (4.3 to 27.4)	20.6 (8.7 to 37.9)	44.8 (26.4 to 64.3)	11.1 (2.4 to 29.2)
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	8.6 (1.8 to 23.1)	21.9 (9.3 to 40.0)	36 (18.0 to 57.5)	11.5 (2.4 to 30.2)
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	35.7 (18.6 to 55.9)	71 (52.0 to 85.8)	54.5 (32.2 to 75.6)	36 (18.0 to 57.5)
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	20.7 (8.0 to 39.7)	40 (22.7 to 59.4)	30.4 (13.2 to 52.9)	20.8 (7.1 to 42.2)
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	24.1 (10.3 to 43.5)	31 (15.3 to 50.8)	28.6 (11.3 to 52.2)	23.8 (8.2 to 47.2)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	37	41
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	57.1 (41.0 to 72.3)	90.5 (77.4 to 97.3)	62.2 (44.8 to 77.5)	26.8 (14.2 to 42.9)
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	17.9 (7.5 to 33.5)	77.1 (59.9 to 89.6)	35.3 (19.7 to 53.5)	2.9 (0.1 to 15.3)
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	8.3 (1.8 to 22.5)	69.7 (51.3 to 84.4)	26.7 (12.3 to 45.9)	5.9 (0.7 to 19.7)
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	6.5 (0.8 to 21.4)	58.1 (39.1 to 75.5)	16 (4.5 to 36.1)	3.3 (0.1 to 17.2)
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	82.8 (64.2 to 94.2)	96.6 (82.2 to 99.9)	36.4 (17.2 to 59.3)	50 (29.9 to 70.1)
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	54.8 (36.0 to 72.7)	74.1 (53.7 to 88.9)	20 (5.7 to 43.7)	18.5 (6.3 to 38.1)
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	48 (27.8 to 68.7)	56 (34.9 to 75.6)	20 (5.7 to 43.7)	16 (4.5 to 36.1)

Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	45.2 (29.8 to 61.3)	52.4 (36.4 to 68.0)	21.6 (9.8 to 38.2)	19.5 (8.8 to 34.9)
Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	20.5 (9.3 to 36.5)	48.6 (31.4 to 66.0)	14.7 (5.0 to 31.1)	5.9 (0.7 to 19.7)
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	11.1 (3.1 to 26.1)	39.4 (22.9 to 57.9)	16.7 (5.6 to 34.7)	11.8 (3.3 to 27.5)
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	6.5 (0.8 to 21.4)	29 (14.2 to 48.0)	8 (1.0 to 26.0)	3.3 (0.1 to 17.2)
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	55.2 (35.7 to 73.6)	55.2 (35.7 to 73.6)	18.2 (5.2 to 40.3)	15.4 (4.4 to 34.9)
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	19.4 (7.5 to 37.5)	29.6 (13.8 to 50.2)	5 (0.1 to 24.9)	7.4 (0.9 to 24.3)
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	20 (6.8 to 40.7)	12 (2.5 to 31.2)	10 (1.2 to 31.7)	8 (1.0 to 26.0)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	48.7 (32.4 to 65.2)	12.5 (4.2 to 26.8)		
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	42.9 (26.3 to 60.6)	5.3 (0.6 to 17.7)		
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	33.3 (18.0 to 51.8)	0 (0.0 to 10.3)		
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	23.3 (9.9 to 42.3)	0 (0.0 to 11.2)		
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	63 (42.4 to 80.6)	6.9 (0.8 to 22.8)		
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	37 (19.4 to 57.6)	4 (0.1 to 20.4)		
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	32 (14.9 to 53.5)	4.3 (0.1 to 21.9)		
Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	20.5 (9.3 to 36.5)	15 (5.7 to 29.8)		
Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	25.7 (12.5 to 43.3)	5.3 (0.6 to 17.7)		
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	24.2 (11.1 to 42.3)	0 (0.0 to 10.3)		
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	13.3 (3.8 to 30.7)	0 (0.0 to 11.2)		
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	25.9 (11.1 to 46.3)	6.9 (0.8 to 22.8)		
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	11.1 (2.4 to 29.2)	4 (0.1 to 20.4)		
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	12 (2.5 to 31.2)	0 (0.0 to 14.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with a ≥ 10-fold increase of anti-H2 and anti-H18 antibody concentration measured by ELISA

End point title	Percentage of subjects with a ≥ 10-fold increase of anti-H2 and anti-H18 antibody concentration measured by ELISA

End point description:

Percentage of subjects with a ≥ 10-fold increase of anti-H2 and anti-H18 antibody concentration, from Day 1, is calculated with exact 95% CI by ELISA .

End point type	Secondary

End point timeframe:

At Day 29, at Day 85, Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	41	40
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	67.4 (51.5 to 80.9)	15 (5.7 to 29.8)	68.3 (51.9 to 81.9)	42.5 (27.0 to 59.1)
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	25.6 (13.0 to 42.1)	5.6 (0.7 to 18.7)	55.9 (37.9 to 72.8)	22.9 (10.4 to 40.1)
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	15.4 (5.9 to 30.5)	0 (0.0 to 10.3)	26.7 (12.3 to 45.9)	11.1 (2.4 to 29.2)
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	14.3 (4.8 to 30.3)	0 (0.0 to 10.9)	23.1 (9.0 to 43.6)	11.5 (2.4 to 30.2)
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	25 (10.7 to 44.9)	71 (52.0 to 85.8)	65.2 (42.7 to 83.6)	24 (9.4 to 45.1)
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	13.8 (3.9 to 31.7)	23.3 (9.9 to 42.3)	25 (9.8 to 46.7)	20.8 (7.1 to 42.2)
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	13.8 (3.9 to 31.7)	13.8 (3.9 to 31.7)	18.2 (5.2 to 40.3)	9.5 (1.2 to 30.4)
Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	23.3 (11.8 to 38.6)	15 (5.7 to 29.8)	25 (12.7 to 41.2)	12.5 (4.2 to 26.8)
Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	7.7 (1.6 to 20.9)	2.8 (0.1 to 14.5)	24.2 (11.1 to 42.3)	5.7 (0.7 to 19.2)
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	2.6 (0.1 to 13.5)	0 (0.0 to 10.3)	6.9 (0.8 to 22.8)	3.7 (0.1 to 19.0)
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	0 (0.0 to 10.0)	0 (0.0 to 10.9)	12 (2.5 to 31.2)	3.8 (0.1 to 19.6)
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	17.9 (6.1 to 36.9)	25.8 (11.9 to 44.6)	18.2 (5.2 to 40.3)	12 (2.5 to 31.2)
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	6.9 (0.8 to 22.8)	13.3 (3.8 to 30.7)	4.3 (0.1 to 21.9)	4.2 (0.1 to 21.1)
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	6.9 (0.8 to 22.8)	10.3 (2.2 to 27.4)	4.8 (0.1 to 23.8)	4.8 (0.1 to 23.8)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	37	41
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	16.7 (7.0 to 31.4)	61.9 (45.6 to 76.4)	18.9 (8.0 to 35.2)	2.4 (0.1 to 12.9)
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	2.6 (0.1 to 13.5)	48.6 (31.4 to 66.0)	20.6 (8.7 to 37.9)	2.9 (0.1 to 15.3)
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	0 (0.0 to 9.7)	12.1 (3.4 to 28.2)	16.7 (5.6 to 34.7)	0 (0.0 to 10.3)
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	0 (0.0 to 11.2)	6.5 (0.8 to 21.4)	8 (1.0 to 26.0)	0 (0.0 to 11.6)
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	48.3 (29.4 to 67.5)	65.5 (45.7 to 82.1)	9.1 (1.1 to 29.2)	15.4 (4.4 to 34.9)
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	25.8 (11.9 to 44.6)	22.2 (8.6 to 42.3)	5 (0.1 to 24.9)	7.4 (0.9 to 24.3)
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	24 (9.4 to 45.1)	12 (2.5 to 31.2)	10 (1.2 to 31.7)	8 (1.0 to 26.0)
Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	16.7 (7.0 to 31.4)	16.7 (7.0 to 31.4)	8.1 (1.7 to 21.9)	2.4 (0.1 to 12.9)
Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	2.6 (0.1 to 13.5)	5.7 (0.7 to 19.2)	2.9 (0.1 to 15.3)	2.9 (0.1 to 15.3)
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	0 (0.0 to 9.7)	3 (0.1 to 15.8)	6.7 (0.8 to 22.1)	2.9 (0.1 to 15.3)
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	0 (0.0 to 11.2)	0 (0.0 to 11.2)	4 (0.1 to 20.4)	0 (0.0 to 11.6)
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	17.2 (5.8 to 35.8)	3.4 (0.1 to 17.8)	4.5 (0.1 to 22.8)	7.7 (0.9 to 25.1)
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	6.5 (0.8 to 21.4)	0 (0.0 to 12.8)	5 (0.1 to 24.9)	3.7 (0.1 to 19.0)
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	8 (1.0 to 26.0)	0 (0.0 to 13.7)	10 (1.2 to 31.7)	0 (0.0 to 13.7)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	20.5 (9.3 to 36.5)	2.5 (0.1 to 13.2)		
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	17.1 (6.6 to 33.6)	5.3 (0.6 to 17.7)		
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	15.2 (5.1 to 31.9)	0 (0.0 to 10.3)		
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	10 (2.1 to 26.5)	0 (0.0 to 11.2)		
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	22.2 (8.6 to 42.3)	3.4 (0.1 to 17.8)		
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	11.1 (2.4 to 29.2)	0 (0.0 to 13.7)		
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	12 (2.5 to 31.2)	0 (0.0 to 14.8)		
Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	7.7 (1.6 to 20.9)	2.5 (0.1 to 13.2)		

Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	11.4 (3.2 to 26.7)	5.3 (0.6 to 17.7)		
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	9.1 (1.9 to 24.3)	0 (0.0 to 10.3)		
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	10 (2.1 to 26.5)	0 (0.0 to 11.2)		
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	11.1 (2.4 to 29.2)	0 (0.0 to 11.9)		
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	11.1 (2.4 to 29.2)	0 (0.0 to 13.7)		
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	8 (1.0 to 26.0)	0 (0.0 to 14.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: MGI for anti-H2 and anti-H18 antibodies concentrations measured by ELISA

End point title	MGI for anti-H2 and anti-H18 antibodies concentrations measured by ELISA

End point description:

MGI is defined as the geometric mean of the fold increase in serum HI concentration post-vaccination compared to Day 1.

End point type	Secondary

End point timeframe:

At Day 29, at Day 85, Month 8, Month 14, Month 14 + 28 days, Month 20 and Month 26, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	41	40
Units: Ratio				
geometric mean (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	18.4 (13.6 to 24.9)	5.3 (4.0 to 7.0)	17.3 (12.9 to 23.1)	9.9 (7.0 to 14.0)
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	7 (5.2 to 9.2)	3.2 (2.5 to 4.2)	9.5 (7.2 to 12.5)	4.4 (3.0 to 6.5)
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	4.8 (3.7 to 6.2)	2.4 (1.9 to 2.9)	6.2 (4.6 to 8.4)	3.1 (2.1 to 4.4)
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	3.6 (2.8 to 4.7)	2.2 (1.8 to 2.6)	5.6 (3.9 to 8.1)	3.1 (2.1 to 4.5)
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	6.1 (4.3 to 8.7)	17.2 (12.5 to 23.8)	14.7 (10.4 to 20.8)	5.1 (3.4 to 7.7)
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	3.9 (3.0 to 5.1)	6.4 (4.8 to 8.7)	6.5 (4.6 to 9.0)	3.6 (2.4 to 5.3)
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	3.5 (2.7 to 4.6)	5 (3.7 to 6.7)	5 (3.5 to 7.1)	3 (2.0 to 4.7)
Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	5.2 (3.9 to 6.9)	4.6 (3.5 to 6.0)	5.3 (3.8 to 7.3)	3.7 (2.8 to 4.9)

Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	2.6 (2.1 to 3.3)	2.9 (2.2 to 3.7)	4.9 (3.7 to 6.5)	2 (1.5 to 2.7)
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	2.4 (1.9 to 2.9)	2.4 (1.9 to 3.0)	3.5 (2.6 to 4.6)	1.8 (1.4 to 2.4)
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	1.9 (1.5 to 2.2)	2.1 (1.7 to 2.6)	3.1 (2.3 to 4.4)	1.8 (1.3 to 2.4)
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	4.1 (2.9 to 5.7)	6.4 (4.6 to 9.0)	4.6 (3.1 to 6.6)	3.3 (2.3 to 4.7)
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	2.5 (1.9 to 3.1)	3.5 (2.6 to 4.8)	2.7 (2.0 to 3.8)	2.2 (1.6 to 3.1)
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	2.4 (1.8 to 3.0)	2.9 (2.1 to 3.9)	2.4 (1.7 to 3.4)	2.1 (1.5 to 3.1)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	37	41
Units: Ratio				
geometric mean (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	4.7 (3.7 to 6.0)	12.3 (9.2 to 16.3)	5.6 (3.8 to 8.1)	2.3 (1.8 to 2.9)
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	2.4 (2.0 to 2.9)	8.2 (6.3 to 10.7)	4.1 (2.8 to 5.8)	1.7 (1.4 to 2.0)
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	1.8 (1.5 to 2.1)	5.2 (4.0 to 6.6)	3.3 (2.2 to 4.9)	1.5 (1.3 to 1.8)
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	1.6 (1.4 to 2.0)	4.1 (3.3 to 5.3)	2.5 (1.8 to 3.6)	1.4 (1.2 to 1.7)
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	12.1 (8.0 to 18.3)	12.6 (9.7 to 16.2)	3.3 (2.3 to 4.8)	5.6 (3.7 to 8.4)
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	4.8 (3.4 to 6.9)	6.2 (4.8 to 8.0)	2.5 (1.7 to 3.6)	2.7 (1.9 to 3.9)
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	4.2 (2.8 to 6.1)	4.9 (3.7 to 6.5)	2.6 (1.7 to 3.9)	2.3 (1.6 to 3.4)
Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	4.1 (3.2 to 5.3)	4.3 (3.3 to 5.6)	2.7 (2.0 to 3.7)	2.1 (1.7 to 2.7)
Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	2.2 (1.8 to 2.7)	4.3 (3.4 to 5.3)	2 (1.5 to 2.7)	1.6 (1.4 to 2.0)
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	1.8 (1.5 to 2.2)	3.2 (2.6 to 3.9)	2 (1.5 to 2.7)	1.6 (1.3 to 2.0)
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	1.6 (1.3 to 2.0)	2.6 (2.1 to 3.3)	1.7 (1.2 to 2.3)	1.3 (1.1 to 1.5)
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	4.4 (3.3 to 5.9)	4.3 (3.4 to 5.3)	2.4 (1.8 to 3.3)	2.4 (1.8 to 3.2)
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	2.4 (1.9 to 3.1)	2.8 (2.3 to 3.5)	2 (1.4 to 2.8)	1.6 (1.3 to 2.0)
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	2.2 (1.6 to 3.0)	2.5 (2.0 to 3.1)	2.1 (1.4 to 3.2)	1.4 (1.1 to 1.8)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		

Units: Ratio				
geometric mean (confidence interval 95%)				
Anti-H2, Day 29 (N=43;40;41;40;42;42;37;41;39;40)	5 (3.5 to 7.0)	1.9 (1.6 to 2.3)		
Anti-H2, Day 85 (N=39;36;34;35;39;35;34;34;35;38)	4.2 (2.9 to 6.1)	1.6 (1.3 to 1.9)		
Anti-H2, M8 (N=39;34;30;27;36;33;30;34;33;34)	3.3 (2.3 to 4.7)	1.5 (1.3 to 1.7)		
Anti-H2, M14 (N=35;32;26;26;31;31;25;30;30;31)	2.8 (2.0 to 4.0)	1.4 (1.2 to 1.6)		
Anti-H2, M14+28d(N=28;31;23;25;29;29;22;26	6.1 (4.2 to 8.9)	1.9 (1.5 to 2.3)		
Anti-H2, M20 (N=29;30;24;24;31;27;20;27;27;25)	3.7 (2.6 to 5.2)	1.3 (1.1 to 1.6)		
Anti-H2, M26 (N=29;29;22;21;25;25;20;25;25;23)	3.2 (2.2 to 4.6)	1.4 (1.2 to 1.6)		
Anti-H18, Day 29 (N=43;40;40;40;42;42;37;41;39;40)	2.5 (1.9 to 3.3)	2 (1.7 to 2.4)		
Anti-H18, Day 85 (N=39;36;33;35;39;35;34;34;35;38)	2.6 (1.9 to 3.6)	1.6 (1.3 to 1.9)		
Anti-H18, M8 (N=39;34;29;27;36;33;30;34;33;34)	2.3 (1.7 to 3.2)	1.5 (1.3 to 1.7)		
Anti-H18, M14 (N=35;32;25;26;31;31;25;30;30;31)	1.9 (1.4 to 2.5)	1.3 (1.1 to 1.5)		
Anti-H18, M14+28d(N=28;31;22;25;29;29;22;26	2.6 (1.8 to 3.6)	1.7 (1.3 to 2.1)		
Anti-H18, M20 (N=29;30;23;24;31;27;20;27;27;25)	2.1 (1.6 to 2.9)	1.3 (1.1 to 1.6)		
Anti-H18, M26 (N=29;29;21;21;25;25;20;25;25;23)	1.9 (1.3 to 2.8)	1.4 (1.2 to 1.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for anti-H1N1 swine influenza and anti-IIV4-H1N1 anti-bodies measured by MN assay

End point title	Titers for anti-H1N1 swine influenza and anti-IIV4-H1N1 anti-bodies measured by MN assay

End point description:

Titers are presented as GMTs and measured by MN assay. MN cut-off = 20 1/DIL

End point type	Secondary

End point timeframe:

At Days 1, 29 and 85

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	46	46
Units: Titer				
geometric mean (confidence interval 95%)				
Day 1 (N=45;46;46;46;47;47;47;46;44;45)	58.8 (45.6 to 75.7)	61 (47.8 to 77.8)	62.9 (50.8 to 77.8)	51.7 (39.5 to 67.6)
Day 29 (N=43;40;40;40;41;42;37;41;39;40)	84 (68.8 to 102.5)	93.5 (76.7 to 113.9)	87.2 (77.0 to 98.8)	84.3 (74.2 to 95.7)
Day 85 (N=39;36;34;35;38;35;34;34;35;38)	65.8 (49.6 to 87.2)	89.8 (73.7 to 109.5)	96.1 (83.8 to 110.2)	56 (45.3 to 69.2)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	47	47	46
Units: Titer				
geometric mean (confidence interval 95%)				
Day 1 (N=45;46;46;46;47;47;47;46;44;45)	53.7 (42.6 to 67.7)	56.2 (44.5 to 70.8)	56.2 (45.6 to 69.1)	70.9 (57.3 to 87.8)
Day 29 (N=43;40;40;40;41;42;37;41;39;40)	93.1 (82.2 to 105.5)	80 (67.8 to 94.4)	71.5 (59.4 to 86.0)	78.7 (64.9 to 95.4)
Day 85 (N=39;36;34;35;38;35;34;34;35;38)	81.5 (68.1 to 97.5)	86.6 (73.7 to 101.7)	63.9 (51.7 to 79.1)	68 (52.8 to 87.5)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	45		
Units: Titer				
geometric mean (confidence interval 95%)				
Day 1 (N=45;46;46;46;47;47;47;46;44;45)	56.6 (45.2 to 70.8)	60.6 (48.9 to 75.2)		
Day 29 (N=43;40;40;40;41;42;37;41;39;40)	69.4 (54.1 to 88.9)	103.7 (88.0 to 122.3)		
Day 85 (N=39;36;34;35;38;35;34;34;35;38)	84.9 (72.6 to 99.3)	99.6 (78.5 to 126.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-H1N1 swine influenza and anti-

IIV4-H1N1 antibodies measured by MN assay

End point title	Number of seropositive subjects for anti-H1N1 swine influenza and anti-IIV4-H1N1 antibodies measured by MN assay

End point description:

Anti-H1N1 swine influenza and anti-IIV4-H1N1 immune response measured by MN assay. A seropositive subject is a subject whose titer is greater than or equal to the cut-off value: cut-off = 20 1/DIL.

End point type	Secondary

End point timeframe:

At Days 1, 29 and 85

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	46	46
Units: Participants				
Day 1 (N=45;46;46;46;47;47;47;46;44;45)	40	41	43	38
Day 29 (N=43;40;40;40;41;42;37;41;39;40)	42	39	40	40
Day 85 (N=39;36;34;35;38;35;34;34;35;38)	36	35	34	34

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	47	47	46
Units: Participants				
Day 1 (N=45;46;46;46;47;47;47;46;44;45)	42	42	44	43
Day 29 (N=43;40;40;40;41;42;37;41;39;40)	41	42	37	40
Day 85 (N=39;36;34;35;38;35;34;34;35;38)	38	35	34	32

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	45		
Units: Participants				
Day 1 (N=45;46;46;46;47;47;47;46;44;45)	42	43		
Day 29 (N=43;40;40;40;41;42;37;41;39;40)	36	40		
Day 85 (N=39;36;34;35;38;35;34;34;35;38)	35	37		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with a ≥ 4-fold increase of anti-H1N1 swine influenza and anti-IIV4-H1N1 antibody titers measured by MN assay

End point title	Percentage of subjects with a ≥ 4-fold increase of anti-H1N1 swine influenza and anti-IIV4-H1N1 antibody titers measured by MN assay

End point description:

Percentage of subjects with a ≥ 4-fold increase of anti-H1N1 swine influenza and anti-IIV4-H1N1 antibody titers, from Day 1, is calculated with exact 95% CI by MN assay.

End point type	Secondary

End point timeframe:

At Day 29 and Day 85, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	39	39
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 29 (N=43;40;39;39;41;42;37;41;39;40)	9.3 (2.6 to 22.1)	22.5 (10.8 to 38.5)	7.7 (1.6 to 20.9)	23.1 (11.1 to 39.3)
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	5.1 (0.6 to 17.3)	16.7 (6.4 to 32.8)	18.2 (7.0 to 35.5)	5.9 (0.7 to 19.7)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	42	37	41
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 29 (N=43;40;39;39;41;42;37;41;39;40)	24.4 (12.4 to 40.3)	9.5 (2.7 to 22.6)	10.8 (3.0 to 25.4)	2.4 (0.1 to 12.9)
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	21.1 (9.6 to 37.3)	14.3 (4.8 to 30.3)	5.9 (0.7 to 19.7)	0 (0.0 to 10.3)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 29 (N=43;40;39;39;41;42;37;41;39;40)	7.7 (1.6 to 20.9)	15 (5.7 to 29.8)		
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	8.6 (1.8 to 23.1)	15.8 (6.0 to 31.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with a ≥ 10-fold increase of anti-H1N1 swine influenza and anti-IIV4-H1N1 antibody titers measured by MN assay

End point title	Percentage of subjects with a ≥ 10-fold increase of anti-H1N1 swine influenza and anti-IIV4-H1N1 antibody titers measured by MN assay

End point description:

Percentage of subjects with a ≥ 10-fold increase of anti-H1N1 swine influenza and anti-IIV4-H1N1 antibody titers, from Day 1, is calculated with exact 95% CI by MN assay.

End point type	Secondary

End point timeframe:

At Day 29 and Day 85, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	39	39
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 29 (N=43;40;39;39;41;42;37;41;39;40)	2.3 (0.1 to 12.3)	2.5 (0.1 to 13.2)	0 (0.0 to 9.0)	0 (0.0 to 9.0)
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	0 (0.0 to 9.0)	2.8 (0.1 to 14.5)	3 (0.1 to 15.8)	0 (0.0 to 10.3)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	42	37	41
Units: Percentage of subjects				
number (confidence interval 95%)				

Day 29 (N=43;40;39;39;41;42;37;41;39;40)	0 (0.0 to 8.6)	0 (0.0 to 8.4)	0 (0.0 to 9.5)	0 (0.0 to 8.6)
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	0 (0.0 to 9.3)	2.9 (0.1 to 14.9)	0 (0.0 to 10.3)	0 (0.0 to 10.3)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 29 (N=43;40;39;39;41;42;37;41;39;40)	0 (0.0 to 9.0)	0 (0.0 to 8.8)		
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	0 (0.0 to 10.0)	0 (0.0 to 9.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: MGI for anti-H1N1 swine influenza and anti-IIV4-H1N1 antibodies titers measured by MN assay

End point title	MGI for anti-H1N1 swine influenza and anti-IIV4-H1N1 antibodies titers measured by MN assay

End point description:

MGI is defined as the geometric mean of the fold increase in serum HI titer post-vaccination compared to Day 1.

End point type	Secondary

End point timeframe:

At Day 29 and at Day 85, compared to Day 1

End point values	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3	D-SUIV Adjuvanted Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	39	39
Units: Ratio				
geometric mean (confidence interval 95%)				
Day 29 (N=43;40;39;39;41;42;37;41;39;40)	1.4 (1.1 to 1.7)	1.7 (1.3 to 2.1)	1.4 (1.2 to 1.6)	1.7 (1.3 to 2.2)
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	1.1 (0.9 to 1.3)	1.5 (1.1 to 2.0)	1.6 (1.2 to 2.1)	1 (0.9 to 1.3)

End point values	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	42	37	41
Units: Ratio				
geometric mean (confidence interval 95%)				
Day 29 (N=43;40;39;39;41;42;37;41;39;40)	1.7 (1.4 to 2.2)	1.4 (1.2 to 1.7)	1.3 (1.0 to 1.5)	1.1 (0.9 to 1.3)
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	1.5 (1.2 to 1.9)	1.5 (1.2 to 1.9)	1.1 (0.9 to 1.3)	0.9 (0.8 to 1.1)

End point values	D-SUIV Unadjuvanted Group 3	IIV4 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	40		
Units: Ratio				
geometric mean (confidence interval 95%)				
Day 29 (N=43;40;39;39;41;42;37;41;39;40)	1.2 (1.0 to 1.5)	1.7 (1.4 to 2.0)		
Day 85 (N=39;36;33;34;38;35;34;34;35;38)	1.3 (1.1 to 1.6)	1.5 (1.3 to 1.9)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected during the 7-day follow-up period after each vaccination. Unsolicited AEs were collected during the 28-day follow-up period after any vaccination. SAEs were collected during the entire study period (from Day 1 up to Month 26).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	D-SUIV Adjuvanted Group 1

Reporting group description:

Subjects received one dose of D-SUIV cH8/1N1+AS03 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Reporting group title	D-SUIV Adjuvanted Group 2

Reporting group description:

Subjects received one dose of D-SUIV cH5/1N1+AS03 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Reporting group title	D-SUIV Adjuvanted Group 3

Reporting group description:

Subjects received one dose of D-SUIV cH8/1N1+AS03 vaccine at Day 1, one dose D-SUIV cH5/1N1+AS03 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1+AS03 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Reporting group title	D-SUIV Adjuvanted Group 4

Reporting group description:

Subjects received one dose of D-SUIV cH8/1N1+AS01 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Reporting group title	D-SUIV Adjuvanted Group 5

Reporting group description:

Subjects received one dose of D-SUIV cH5/1N1+AS01 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Reporting group title	D-SUIV Adjuvanted Group 6

Reporting group description:

Subjects received one dose of D-SUIV cH8/1N1+AS01 vaccine at Day 1, one dose of D-SUIV cH5/1N1+AS01 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1+AS01 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Reporting group title	D-SUIV Unadjuvanted Group 1

Reporting group description:

Subjects received one dose of D-SUIV cH8/1N1 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH5/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Reporting group title	D-SUIV Unadjuvanted Group 2

Reporting group description:

Subjects received one dose of D-SUIV cH5/1N1 vaccine at Day 1, one dose of Placebo at Day 57 and one booster dose of D-SUIV cH8/1N1 vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Reporting group title	D-SUIV Unadjuvanted Group 3

Reporting group description:

Subjects received one dose of D-SUIV cH8/1N1 vaccine at Day 1, one dose of D-SUIV cH5/1N1 vaccine at Day 57 and one booster dose of D-SUIV cH11/1N1 vaccine at Month 14. All doses were administered

intramuscularly in the non-dominant arm.

Reporting group title	IIV4 Group

Reporting group description:

Subjects received one dose of Fluarix Quadrivalent (IIV4) vaccine at Day 1, one dose of Placebo at Day 57 and one dose of Fluarix Quadrivalent vaccine at Month 14. All doses were administered intramuscularly in the non-dominant arm.

Serious adverse events	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 45 (4.44%)	1 / 46 (2.17%)	1 / 47 (2.13%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma stage II			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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			
Overdose			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (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
Hyperemesis gravidarum			

subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Pre-eclampsia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (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
Reproductive system and breast disorders			
Menometrorrhagia			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Cholelithiasis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Sleep apnoea syndrome			

subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
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			
Suicide attempt			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Musculoskeletal and connective tissue disorders			
Rotator cuff syndrome			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Influenza			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Meningitis viral			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Pyelonephritis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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
Viral infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (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

Wound infection			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (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
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	D-SUIV Adjuvanted Group 4	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 47 (4.26%)	2 / 48 (4.17%)	2 / 47 (4.26%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma stage II			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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			
Overdose			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Hyperemesis gravidarum			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Pre-eclampsia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (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
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Reproductive system and breast disorders			
Menometrorrhagia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Cholelithiasis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (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
Sleep apnoea syndrome			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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			
Suicide attempt			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Rotator cuff syndrome			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Influenza			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (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
Meningitis viral			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Pyelonephritis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (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

Viral infection			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (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
Wound infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (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	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2	D-SUIV Unadjuvanted Group 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	2 / 46 (4.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma stage II			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
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			
Overdose			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Congenital, familial and genetic disorders			
Ankyloglossia congenital			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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

Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Hyperemesis gravidarum			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Pre-eclampsia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Reproductive system and breast disorders			
Menometrorrhagia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Cholelithiasis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Sleep apnoea syndrome			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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			
Suicide attempt			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Musculoskeletal and connective tissue disorders			
Rotator cuff syndrome			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Influenza			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Meningitis viral			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Viral infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Wound infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (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	IIV4 Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 47 (6.38%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma stage II			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Ankyloglossia congenital			

subjects affected / exposed	1 / 47 (2.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperemesis gravidarum			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Menometrorrhagia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			

subjects affected / exposed	1 / 47 (2.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Rotator cuff syndrome			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis viral			

subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Obesity				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	D-SUIV Adjuvanted Group 1	D-SUIV Adjuvanted Group 2	D-SUIV Adjuvanted Group 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 45 (88.89%)	43 / 46 (93.48%)	44 / 47 (93.62%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			

subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Phlebitis superficial			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	9 / 45 (20.00%)	16 / 46 (34.78%)	15 / 47 (31.91%)
occurrences (all)	13	20	20
Cyst			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	25 / 45 (55.56%)	28 / 46 (60.87%)	28 / 47 (59.57%)
occurrences (all)	39	44	50
Influenza like illness			
subjects affected / exposed	4 / 45 (8.89%)	3 / 46 (6.52%)	4 / 47 (8.51%)
occurrences (all)	5	5	7
Injection site bruising			

subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	2 / 45 (4.44%)	4 / 46 (8.70%)	3 / 47 (6.38%)
occurrences (all)	2	4	3
Injection site haematoma			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Injection site haemorrhage			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Injection site hypoaesthesia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injection site lymphadenopathy			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Injection site mass			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	37 / 45 (82.22%)	42 / 46 (91.30%)	41 / 47 (87.23%)
occurrences (all)	66	75	92
Injection site paraesthesia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	3 / 47 (6.38%)
occurrences (all)	1	0	3
Injection site swelling			
subjects affected / exposed	5 / 45 (11.11%)	4 / 46 (8.70%)	5 / 47 (10.64%)
occurrences (all)	6	4	6
Injection site warmth			

subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	2	0	0
Malaise			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	7 / 45 (15.56%)	11 / 46 (23.91%)	8 / 47 (17.02%)
occurrences (all)	7	17	8
Swelling			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Thirst			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Menorrhagia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 45 (2.22%)	1 / 46 (2.17%)	2 / 47 (4.26%)
occurrences (all)	1	1	3
Dysphonia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	2	0	0
Nasal congestion			
subjects affected / exposed	2 / 45 (4.44%)	2 / 46 (4.35%)	2 / 47 (4.26%)
occurrences (all)	2	2	2
Oropharyngeal pain			
subjects affected / exposed	3 / 45 (6.67%)	6 / 46 (13.04%)	1 / 47 (2.13%)
occurrences (all)	3	6	1
Productive cough			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Respiratory disorder			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	1 / 47 (2.13%)
occurrences (all)	0	1	1
Rhinitis allergic			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	1 / 45 (2.22%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	1	1	0

Sneezing			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 45 (2.22%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Body temperature increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	3 / 45 (6.67%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	3	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			

subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Lymphocyte percentage increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Monocyte count increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	2 / 47 (4.26%)
occurrences (all)	1	0	2
Neutrophil count increased			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Neutrophil percentage decreased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
White blood cell count increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Foot fracture			

subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Fractured sacrum			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	1 / 45 (2.22%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Procedural pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	25 / 45 (55.56%)	29 / 46 (63.04%)	30 / 47 (63.83%)
occurrences (all)	37	50	50
Hypoaesthesia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 45 (2.22%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Paraesthesia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Presyncope			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Lymph node pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	2 / 47 (4.26%)
occurrences (all)	1	0	2
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 45 (0.00%)	2 / 46 (4.35%)	1 / 47 (2.13%)
occurrences (all)	0	2	1
Abdominal pain upper			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	1 / 47 (2.13%)
occurrences (all)	0	1	1
Dry mouth			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	10 / 45 (22.22%)	15 / 46 (32.61%)	14 / 47 (29.79%)
occurrences (all)	12	19	22

Gastrointestinal pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 45 (2.22%)	1 / 46 (2.17%)	1 / 47 (2.13%)
occurrences (all)	1	1	1
Toothache			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	12 / 45 (26.67%)	13 / 46 (28.26%)	13 / 47 (27.66%)
occurrences (all)	13	19	17
Back pain			
subjects affected / exposed	1 / 45 (2.22%)	1 / 46 (2.17%)	2 / 47 (4.26%)
occurrences (all)	1	1	2
Coccydynia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	24 / 45 (53.33%)	23 / 46 (50.00%)	30 / 47 (63.83%)
occurrences (all)	37	36	47
Neck pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0

Periostitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	1 / 45 (2.22%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Torticollis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Bacterial vaginosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Eye infection			
subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			

subjects affected / exposed	0 / 45 (0.00%)	1 / 46 (2.17%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 45 (6.67%)	4 / 46 (8.70%)	2 / 47 (4.26%)
occurrences (all)	4	4	3
Oral herpes			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	2 / 47 (4.26%)
occurrences (all)	1	0	2
Pneumonia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	4 / 45 (8.89%)	2 / 46 (4.35%)	2 / 47 (4.26%)
occurrences (all)	4	2	2
Tinea pedis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	2 / 45 (4.44%)	7 / 46 (15.22%)	5 / 47 (10.64%)
occurrences (all)	2	7	5
Urinary tract infection			
subjects affected / exposed	1 / 45 (2.22%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	1
Viral infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 45 (0.00%)	0 / 46 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	D-SUIV Adjuvanted Group 4	D-SUIV Adjuvanted Group 5	D-SUIV Adjuvanted Group 6
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 47 (93.62%)	45 / 48 (93.75%)	44 / 47 (93.62%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Skin papilloma			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Flushing			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Phlebitis superficial			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	13 / 47 (27.66%)	20 / 48 (41.67%)	17 / 47 (36.17%)
occurrences (all)	16	25	21
Cyst			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Energy increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	25 / 47 (53.19%)	25 / 48 (52.08%)	26 / 47 (55.32%)
occurrences (all)	40	48	35
Influenza like illness			
subjects affected / exposed	2 / 47 (4.26%)	2 / 48 (4.17%)	3 / 47 (6.38%)
occurrences (all)	2	3	4
Injection site bruising			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Injection site erythema			

subjects affected / exposed	2 / 47 (4.26%)	2 / 48 (4.17%)	4 / 47 (8.51%)
occurrences (all)	2	2	4
Injection site haematoma			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Injection site lymphadenopathy			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	43 / 47 (91.49%)	42 / 48 (87.50%)	44 / 47 (93.62%)
occurrences (all)	69	76	99
Injection site paraesthesia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Injection site pruritus			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Injection site swelling			
subjects affected / exposed	5 / 47 (10.64%)	4 / 48 (8.33%)	2 / 47 (4.26%)
occurrences (all)	5	4	5
Injection site warmth			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	2	0
Peripheral swelling			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	9 / 47 (19.15%)	6 / 48 (12.50%)	9 / 47 (19.15%)
occurrences (all)	10	9	11
Swelling			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Vaccination site pain			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Menorrhagia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 47 (6.38%)	2 / 48 (4.17%)	1 / 47 (2.13%)
occurrences (all)	3	2	1
Dysphonia			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	3 / 47 (6.38%)	1 / 48 (2.08%)	1 / 47 (2.13%)
occurrences (all)	3	2	2
Oropharyngeal pain			
subjects affected / exposed	5 / 47 (10.64%)	5 / 48 (10.42%)	1 / 47 (2.13%)
occurrences (all)	7	5	1
Productive cough			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Abnormal dreams			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Body temperature increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Lymphocyte count increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Lymphocyte percentage decreased			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Lymphocyte percentage increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Monocyte count increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	3 / 47 (6.38%)	3 / 48 (6.25%)	0 / 47 (0.00%)
occurrences (all)	3	3	0
Neutrophil count increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Neutrophil percentage decreased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	2	1	0
White blood cell count increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Fractured sacrum			

subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	2	0
Headache			
subjects affected / exposed	31 / 47 (65.96%)	25 / 48 (52.08%)	34 / 47 (72.34%)
occurrences (all)	49	42	55
Hypoaesthesia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	2 / 47 (4.26%)
occurrences (all)	0	1	2
Parosmia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Taste disorder			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Lymphadenopathy			
subjects affected / exposed	1 / 47 (2.13%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	1	3	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 47 (0.00%)	3 / 48 (6.25%)	0 / 47 (0.00%)
occurrences (all)	0	3	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye pain			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	2 / 47 (4.26%)
occurrences (all)	0	3	2
Dry mouth			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	11 / 47 (23.40%)	12 / 48 (25.00%)	15 / 47 (31.91%)
occurrences (all)	14	17	19
Gastrointestinal pain			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
Toothache			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 47 (12.77%)	13 / 48 (27.08%)	13 / 47 (27.66%)
occurrences (all)	6	17	18
Back pain			

subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Coccydynia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	27 / 47 (57.45%)	26 / 48 (54.17%)	28 / 47 (59.57%)
occurrences (all)	33	36	44
Neck pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	0	2	0
Pain in jaw			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Periostitis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Polyarthritis			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	1 / 47 (2.13%)
occurrences (all)	3	1	1
Oral herpes			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	1
Otitis media			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Tinea pedis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 47 (8.51%)	3 / 48 (6.25%)	4 / 47 (8.51%)
occurrences (all)	6	3	4
Urinary tract infection			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0

Viral infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	D-SUIV Unadjuvanted Group 1	D-SUIV Unadjuvanted Group 2	D-SUIV Unadjuvanted Group 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 47 (72.34%)	38 / 48 (79.17%)	42 / 46 (91.30%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Melanocytic naevus			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Phlebitis superficial			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	3 / 47 (6.38%)	4 / 48 (8.33%)	5 / 46 (10.87%)
occurrences (all)	3	4	6
Cyst			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	18 / 47 (38.30%)	24 / 48 (50.00%)	18 / 46 (39.13%)
occurrences (all)	24	30	28
Influenza like illness			
subjects affected / exposed	2 / 47 (4.26%)	4 / 48 (8.33%)	1 / 46 (2.17%)
occurrences (all)	3	4	1
Injection site bruising			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Injection site haematoma			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Injection site lymphadenopathy			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	18 / 47 (38.30%)	22 / 48 (45.83%)	23 / 46 (50.00%)
occurrences (all)	24	28	40
Injection site paraesthesia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Injection site pruritus			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Injection site warmth			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	5 / 47 (10.64%)	4 / 48 (8.33%)	6 / 46 (13.04%)
occurrences (all)	6	5	6
Swelling			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Vaccination site pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Menorrhagia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 47 (2.13%)	4 / 48 (8.33%)	2 / 46 (4.35%)
occurrences (all)	1	4	2
Dysphonia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal pain			
subjects affected / exposed	5 / 47 (10.64%)	4 / 48 (8.33%)	6 / 46 (13.04%)
occurrences (all)	5	4	6
Productive cough			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Respiratory tract congestion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Sinus congestion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences (all)	2	0	2
Body temperature increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Lymphocyte percentage increased			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	2
Neutrophil count increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Neutrophil percentage decreased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
White blood cell count increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Eye contusion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Foot fracture			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Fractured sacrum			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	20 / 47 (42.55%)	25 / 48 (52.08%)	20 / 46 (43.48%)
occurrences (all)	26	43	31
Hypoaesthesia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	2
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Myopia			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Photophobia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	2	0
Dry mouth			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	8 / 47 (17.02%)	10 / 48 (20.83%)	12 / 46 (26.09%)
occurrences (all)	8	14	16
Gastrointestinal pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0

Nausea			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 47 (14.89%)	6 / 48 (12.50%)	5 / 46 (10.87%)
occurrences (all)	8	6	6
Back pain			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Coccydynia			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	10 / 47 (21.28%)	14 / 48 (29.17%)	15 / 46 (32.61%)
occurrences (all)	12	15	19
Neck pain			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Periostitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Torticollis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Diarrhoea infectious			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 47 (2.13%)	2 / 48 (4.17%)	0 / 46 (0.00%)
occurrences (all)	1	2	0
Gastroenteritis viral			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 47 (2.13%)	2 / 48 (4.17%)	3 / 46 (6.52%)
occurrences (all)	1	2	3

Oral herpes			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Sinusitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Tinea pedis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	5 / 47 (10.64%)	9 / 48 (18.75%)	7 / 46 (15.22%)
occurrences (all)	6	9	7
Urinary tract infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Viral upper respiratory tract infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	IIV4 Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 47 (93.62%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Melanocytic naevus			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Skin papilloma			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Phlebitis superficial			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		

General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	3 / 47 (6.38%)		
occurrences (all)	5		
Cyst			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Energy increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	15 / 47 (31.91%)		
occurrences (all)	21		
Influenza like illness			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Injection site bruising			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Injection site erythema			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Injection site haematoma			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Injection site haemorrhage			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Injection site hypoaesthesia			

subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Injection site lymphadenopathy				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Injection site mass				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Injection site pain				
subjects affected / exposed	39 / 47 (82.98%)			
occurrences (all)	66			
Injection site paraesthesia				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Injection site pruritus				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Injection site reaction				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Injection site swelling				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Injection site warmth				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Malaise				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Pain				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Peripheral swelling				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Pyrexia				

subjects affected / exposed	6 / 47 (12.77%)		
occurrences (all)	7		
Swelling			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Thirst			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Vaccination site pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Menorrhagia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Dysphonia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Lower respiratory tract congestion			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Nasal congestion			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	2		
Productive cough			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Respiratory disorder			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Respiratory tract congestion			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Sinus congestion			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Sneezing			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		

Insomnia			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Body temperature increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Lymphocyte count increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Lymphocyte percentage increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Monocyte count increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Neutrophil count increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Neutrophil percentage decreased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
White blood cell count increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Eye contusion			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Foot fracture			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Fractured sacrum			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Limb injury			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Muscle strain			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Procedural pain			
subjects affected / exposed	2 / 47 (4.26%)		
occurrences (all)	2		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	23 / 47 (48.94%)		
occurrences (all)	28		
Hypoaesthesia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Parosmia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Taste disorder			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Leukopenia			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Lymph node pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Eye pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Myopia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Photophobia			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	2		
Dry mouth			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorder			
subjects affected / exposed	9 / 47 (19.15%)		
occurrences (all)	10		
Gastrointestinal pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		

Toothache			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	2 / 47 (4.26%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 47 (10.64%)		
occurrences (all)	8		
Back pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Coccydynia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Flank pain			

subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Joint swelling				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Muscle spasms				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Musculoskeletal stiffness				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	12 / 47 (25.53%)			
occurrences (all)	17			
Neck pain				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Pain in extremity				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Pain in jaw				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Periostitis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Polyarthritis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Rotator cuff syndrome				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Tendonitis				

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Torticollis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Bacterial vaginosis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Diarrhoea infectious			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Eye infection			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	2 / 47 (4.26%)		
occurrences (all)	2		
Gastroenteritis viral			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		

Otitis media				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Tinea pedis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Tooth infection				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Upper respiratory tract infection				
subjects affected / exposed	4 / 47 (8.51%)			
occurrences (all)	5			
Urinary tract infection				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Viral infection				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Viral upper respiratory tract infection				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			

Vulvovaginal candidiasis subjects affected / exposed occurrences (all) Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0 0 / 47 (0.00%) 0		
Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 July 2019	• The cell-mediated immune response was not assessed at Month 14 and later timepoints. The blood sampling for cell-mediated immunity at Visit 12 (Month 26) has been removed. • The hemagglutination inhibition assay (HI) was not performed on the inactivated influenza quadrivalent vaccine H1N1 component, cH11/1N1, cH6/1N5, H5N8 and H1N1 swine flu strains. For cH5/1N1 and cH8/1N1, the HI assay was only performed until Visit 6 (Day 85). • The micro-neutralisation (MN) assay was only performed for cH6/1N5 and H1N1 until Visit 6 (Day 85). MN assay was not performed for H5N8. • The anti-group 2 hemagglutinin (HA) stalk response by ELISA was not performed. • The immune response in terms of anti-neuraminidase antibodies was not assessed. • The passive transfer experiment in mice was not performed for the Month 14 and Month 26 time points. The blood collection at Month 26 for passive transfer has been removed. • The anti-H9 full length HA ELISA was not performed. • Anti-stalk antibody functionality was not further investigated, except for the antibody-dependent cell-mediated cytotoxicity until the interim analysis at Day 85. • Occurrence of RT-PCR-confirmed influenza cases endpoint was removed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported