



Clinical trial results:

Safety of a Quadrivalent Influenza Vaccine (VaxigripTetra™) in Subjects Aged 6 Months and Older in Vietnam

Summary

EudraCT number	2019-002218-38
Trial protocol	Outside EU/EEA
Global end of trial date	17 March 2019

Results information

Result version number	v1 (current)
This version publication date	04 October 2019
First version publication date	04 October 2019

Trial information

Trial identification

Sponsor protocol code	GQM10
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03765437
WHO universal trial number (UTN)	U1111-1183-6274

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur
Sponsor organisation address	14 Espace Henry Vallée, Lyon, France, 69007
Public contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 August 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	17 March 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety of the Quadrivalent influenza vaccine (QIV) after each and any vaccination according to subjects' age group.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 January 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Vietnam: 230
Worldwide total number of subjects	230
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	44
Children (2-11 years)	134
Adolescents (12-17 years)	4
Adults (18-64 years)	41
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 1 centre in Vietnam from 15 January 2019 to 17 March 2019.

Pre-assignment

Screening details:

A total of 230 subjects were enrolled in the study.

Period 1

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

Arms

Arm title	Quadrivalent Influenza Vaccine (VaxigripTetra)
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Arm description:

Subjects received either 1 or 2 doses of the QIV based on their age and influenza vaccination history.

Arm type	Experimental
Investigational medicinal product name	Sanofi Pasteur licensed quadrivalent influenza vaccine (split-virion, inactivated)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use, Subcutaneous use

Dosage and administration details:

0.5 mL, intramuscular or deep subcutaneous injection, either 1 or 2 doses based on the age and influenza vaccination history of subjects.

Number of subjects in period 1	Quadrivalent Influenza Vaccine (VaxigripTetra)
Started	230
Completed	224
Not completed	6
Consent withdrawn by subject	5
Adverse Event	1

Baseline characteristics

Reporting groups

Reporting group title	Quadrivalent Influenza Vaccine (VaxigripTetra)
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Reporting group description:

Subjects received either 1 or 2 doses of the QIV based on their age and influenza vaccination history.

Reporting group values	Quadrivalent Influenza Vaccine (VaxigripTetra)	Total	
Number of subjects	230	230	
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)	44	44	
Children (2-11 years)	134	134	
Adolescents (12-17 years)	4	4	
Adults (18-64 years)	41	41	
From 65-84 years	7	7	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	13.9		
standard deviation	± 20.6	-	
Gender categorical			
Units: Subjects			
Female	116	116	
Male	114	114	

End points

End points reporting groups

Reporting group title	Quadrivalent Influenza Vaccine (VaxigripTetra)
Reporting group description: Subjects received either 1 or 2 doses of the QIV based on their age and influenza vaccination history.	
Subject analysis set title	Quadrivalent Influenza Vaccine: 6 to 23 months
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects aged 6 to 23 months received either 1 or 2 doses of the QIV based on their influenza vaccination history.	
Subject analysis set title	Quadrivalent Influenza Vaccine: 24 to 35 months
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects aged 24 to 35 months received either 1 or 2 doses of the QIV based on their influenza vaccination history.	
Subject analysis set title	Quadrivalent Influenza Vaccine: 6 to 35 months
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects aged 6 to 35 months received either 1 or 2 doses of the QIV based on their influenza vaccination history.	
Subject analysis set title	Quadrivalent Influenza Vaccine: 3 to 8 years
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects aged 3 to 8 years received either 1 or 2 doses of the QIV based on their influenza vaccination history.	
Subject analysis set title	Quadrivalent Influenza Vaccine: 9 to 17 years
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects aged 9 to 17 years received 1 dose of the QIV.	
Subject analysis set title	Quadrivalent Influenza Vaccine: 18 to 60 years
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects aged 18 to 60 years received 1 dose of the QIV.	
Subject analysis set title	Quadrivalent Influenza Vaccine: Greater Than (>) 60 years
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects aged >60 years received 1 dose of the QIV.	

Primary: Number of Subjects Reporting Immediate Systemic adverse Events (AEs)

End point title	Number of Subjects Reporting Immediate Systemic adverse Events (AEs) ^[1]
End point description: Immediate events were recorded to capture medically relevant unsolicited systemic AEs (including those related to the product administered) that occurred within the first 30 minutes after vaccination. Analysis was performed on safety analysis set (SafAS) which included subjects who had received at least 1 dose of the study vaccine. Here 'n' signifies number of subjects with available data for specified category.	
End point type	Primary
End point timeframe: During the 30 minutes following the vaccination	

Notes:

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

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Quadrivalent Influenza Vaccine (VaxigripTetra)			
Subject group type	Reporting group			
Number of subjects analysed	228			
Units: subjects				
6 to 35 months (n=78)	0			
3 to 8 years (n=80)	0			
9 to 17 years (n=22)	0			
18 to 60 years (n=28)	0			
>60 years (n=20)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Solicited Injection (Inj.) Site Reactions and Systemic Reactions

End point title	Number of Subjects Reporting Solicited Injection (Inj.) Site Reactions and Systemic Reactions ^[2]
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End point description:

Number of subjects experiencing at least 1 solicited injection site reaction (tenderness/pain, erythema, swelling, induration and ecchymosis) and at least 1 systemic reaction (fever [all age groups], headache, malaise, myalgia, shivering [for subjects aged ≥ 2 years], vomiting, crying abnormal, drowsiness, appetite lost and irritability [for subjects ≤ 23 months]) were reported. Analysis was performed on SafAS. Here, "99999" in the data field signifies that the subjects were not evaluable for the specified category for that arm. Here, 'n' = subjects with available data for each specified category.

End point type	Primary
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End point timeframe:

From Day (D)0 to D7 after the vaccination

Notes:

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

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Quadrivalent Influenza Vaccine: 6 to 23 months	Quadrivalent Influenza Vaccine: 24 to 35 months	Quadrivalent Influenza Vaccine: 6 to 35 months	Quadrivalent Influenza Vaccine: 3 to 8 years
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	44	34	78	80
Units: subjects with at least 1 reaction				
Solicited reaction (n=44,34,78,80,22,28,20)	20	11	31	32
Inj. site reaction (n=44,34,78,80,22,28,20)	17	8	25	31
Inj. site tenderness/pain (n=44,34,78,80,22,28,20)	16	6	22	26

Inj. site erythema (n=44,34,78,80,22,28,20)	5	2	7	8
Inj. site swelling (n=44,34,78,80,22,28,20)	0	0	0	4
Inj. site induration (n=44,34,78,80,22,28,20)	0	0	0	5
Inj. site ecchymosis (n=44,34,78,80,22,28,20)	0	0	0	3
Systemic reaction (n=44,34,78,80,22,28,20)	13	4	17	9
Fever (n=44,34,78,80,22,28,20)	6	1	7	4
Headache (n=0,34,34,80,22,28,20)	99999	2	2	4
Malaise (n=0,34,34,80,22,28,20)	99999	2	2	3
Myalgia (n=0,34,34,80,22,28,20)	99999	0	0	4
Shivering (n=0,34,34,80,22,28,20)	99999	0	0	1
Vomiting (n=44,0,44,0,0,0,0)	2	99999	2	99999
Crying abnormal (n=44,0,44,0,0,0,0)	5	99999	5	99999
Drowsiness (n=44,0,44,0,0,0,0)	2	99999	2	99999
Appetite lost (n=44,0,44,0,0,0,0)	6	99999	6	99999
Irritability (n=44,0,44,0,0,0,0)	2	99999	2	99999

End point values	Quadrivalent Influenza Vaccine: 9 to 17 years	Quadrivalent Influenza Vaccine: 18 to 60 years	Quadrivalent Influenza Vaccine: Greater Than (>) 60 years	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	22	28	20	
Units: subjects with at least 1 reaction				
Solicited reaction (n=44,34,78,80,22,28,20)	2	5	3	
Inj. site reaction (n=44,34,78,80,22,28,20)	2	5	2	
Inj. site tenderness/pain (n=44,34,78,80,22,28,20)	2	5	1	
Inj. site erythema (n=44,34,78,80,22,28,20)	0	0	1	
Inj. site swelling (n=44,34,78,80,22,28,20)	0	0	0	
Inj. site induration (n=44,34,78,80,22,28,20)	0	0	0	
Inj. site ecchymosis (n=44,34,78,80,22,28,20)	0	0	0	
Systemic reaction (n=44,34,78,80,22,28,20)	0	2	2	
Fever (n=44,34,78,80,22,28,20)	0	0	0	
Headache (n=0,34,34,80,22,28,20)	0	1	1	
Malaise (n=0,34,34,80,22,28,20)	0	0	0	
Myalgia (n=0,34,34,80,22,28,20)	0	1	1	
Shivering (n=0,34,34,80,22,28,20)	0	0	0	
Vomiting (n=44,0,44,0,0,0,0)	99999	99999	99999	
Crying abnormal (n=44,0,44,0,0,0,0)	99999	99999	99999	
Drowsiness (n=44,0,44,0,0,0,0)	99999	99999	99999	
Appetite lost (n=44,0,44,0,0,0,0)	99999	99999	99999	
Irritability (n=44,0,44,0,0,0,0)	99999	99999	99999	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Unsolicited Non-Serious Adverse Events (AEs)

End point title	Number of Subjects Reporting Unsolicited Non-Serious Adverse Events (AEs) ^[3]
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End point description:

An unsolicited AE was an observed AE that did not fulfill the conditions prelisted in the CRB in terms of diagnosis and/or onset window post-vaccination. Analysis was performed on SafAS. Here 'n' signifies number of subjects with available data for specified category.

End point type	Primary
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End point timeframe:

From D0 to D28 after the vaccination

Notes:

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

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Quadrivalent Influenza Vaccine (VaxigripTetra)			
Subject group type	Reporting group			
Number of subjects analysed	228			
Units: subjects				
6 to 35 months (n=78)	26			
3 to 8 years (n=80)	4			
9 to 17 years (n=22)	0			
18 to 60 years (n=28)	1			
>60 years (n=20)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Serious Adverse Events (SAEs)

End point title	Number of Subjects Reporting Serious Adverse Events (SAEs) ^[4]
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End point description:

SAE was defined as any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a medically important event. Analysis was performed on SafAS. Here 'n' signifies number of subjects with available data for specified category.

End point type	Primary
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End point timeframe:

From D0 to the end of the study (up to 28 days post-vaccination)

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: Only descriptive data was planned to be reported for this endpoint.

End point values	Quadrivalent Influenza Vaccine (VaxigripTetra)			
Subject group type	Reporting group			
Number of subjects analysed	228			
Units: subjects				
6 to 35 months (n=78)	0			
3 to 8 years (n=80)	1			
9 to 17 years (n=22)	0			
18 to 60 years (n=28)	0			
>60 years (n=20)	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AE data collected from D0 up to 28 days post-vaccination. Data reported for overall population of 6 to 35 months as well for separate population of 6 to 23 months and 24 to 35 months.

Adverse event reporting additional description:

Solicited adverse reaction (SAR): An AE, i.e. prelisted in CRB and considered related to vaccination. SAR is thus an adverse drug reaction observed, reported under the conditions (nature and onset) prelisted (i.e.solicited) in CRB. Unsolicited AE: an observed AE that does not fulfill conditions prelisted in CRB.

Analysis was performed on SafAS.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Quadrivalent Influenza Vaccine: 6 to 23 months
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Reporting group description:

Subjects aged 6 to 23 months received either 1 or 2 doses of the QIV based on their influenza vaccination history.

Reporting group title	Quadrivalent Influenza Vaccine: 24 to 35 months
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Reporting group description:

Subjects aged 24 to 35 months received either 1 or 2 doses of the QIV based on their influenza vaccination history.

Reporting group title	Quadrivalent Influenza Vaccine: 6 to 35 months
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Reporting group description:

Subjects aged 6 to 35 months received either 1 or 2 doses of the QIV based on their influenza vaccination history.

Reporting group title	Quadrivalent Influenza Vaccine: 3 to 8 years
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Reporting group description:

Subjects aged 3 to 8 years received either 1 or 2 doses of the QIV based on their influenza vaccination history.

Reporting group title	Quadrivalent Influenza Vaccine: 9 to 17 years
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Reporting group description:

Subjects aged 9 to 17 years received 1 dose of the QIV.

Reporting group title	Quadrivalent Influenza Vaccine: 18 to 60 years
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Reporting group description:

Subjects aged 18 to 60 years received 1 dose of the QIV.

Reporting group title	Quadrivalent Influenza Vaccine: >60 years
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Reporting group description:

Subjects aged >60 years received 1 dose of the QIV.

Serious adverse events	Quadrivalent Influenza Vaccine: 6 to 23 months	Quadrivalent Influenza Vaccine: 24 to 35 months	Quadrivalent Influenza Vaccine: 6 to 35 months
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 44 (0.00%)	0 / 34 (0.00%)	0 / 78 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Injury, poisoning and procedural complications			
Multiple Injuries			
subjects affected / exposed	0 / 44 (0.00%)	0 / 34 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Quadrivalent Influenza Vaccine: 3 to 8 years	Quadrivalent Influenza Vaccine: 9 to 17 years	Quadrivalent Influenza Vaccine: 18 to 60 years
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 80 (1.25%)	0 / 22 (0.00%)	0 / 28 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Multiple Injuries			
subjects affected / exposed	1 / 80 (1.25%)	0 / 22 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Quadrivalent Influenza Vaccine: >60 years		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Multiple Injuries			
subjects affected / exposed	0 / 20 (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: 5 %

Non-serious adverse events	Quadrivalent Influenza Vaccine: 6 to 23 months	Quadrivalent Influenza Vaccine: 24 to 35 months	Quadrivalent Influenza Vaccine: 6 to 35 months
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 44 (56.82%)	18 / 34 (52.94%)	43 / 78 (55.13%)

Nervous system disorders			
Headache			
subjects affected / exposed	0 / 44 (0.00%)	2 / 34 (5.88%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
General disorders and administration site conditions			
Crying			
subjects affected / exposed	5 / 44 (11.36%)	0 / 34 (0.00%)	5 / 78 (6.41%)
occurrences (all)	6	0	6
Injection Site Erythema			
subjects affected / exposed	5 / 44 (11.36%)	2 / 34 (5.88%)	7 / 78 (8.97%)
occurrences (all)	5	2	7
Injection Site Induration			
subjects affected / exposed	0 / 44 (0.00%)	0 / 34 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Injection Site Pain			
subjects affected / exposed	16 / 44 (36.36%)	6 / 34 (17.65%)	22 / 78 (28.21%)
occurrences (all)	18	6	24
Malaise			
subjects affected / exposed	0 / 44 (0.00%)	2 / 34 (5.88%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Pyrexia			
subjects affected / exposed	6 / 44 (13.64%)	1 / 34 (2.94%)	7 / 78 (8.97%)
occurrences (all)	7	1	8
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 44 (13.64%)	7 / 34 (20.59%)	13 / 78 (16.67%)
occurrences (all)	7	7	14
Pharyngitis			
subjects affected / exposed	2 / 44 (4.55%)	4 / 34 (11.76%)	6 / 78 (7.69%)
occurrences (all)	2	4	6
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	6 / 44 (13.64%)	0 / 34 (0.00%)	6 / 78 (7.69%)
occurrences (all)	7	0	7
Non-serious adverse events	Quadrivalent Influenza Vaccine: 3 to 8 years	Quadrivalent Influenza Vaccine: 9 to 17 years	Quadrivalent Influenza Vaccine: 18 to 60 years

Total subjects affected by non-serious adverse events subjects affected / exposed	33 / 80 (41.25%)	2 / 22 (9.09%)	5 / 28 (17.86%)
Nervous system disorders Headache subjects affected / exposed occurrences (all)	4 / 80 (5.00%) 4	0 / 22 (0.00%) 0	1 / 28 (3.57%) 1
General disorders and administration site conditions Crying subjects affected / exposed occurrences (all) Injection Site Erythema subjects affected / exposed occurrences (all) Injection Site Induration subjects affected / exposed occurrences (all) Injection Site Pain subjects affected / exposed occurrences (all) Malaise subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	0 / 80 (0.00%) 0 8 / 80 (10.00%) 8 5 / 80 (6.25%) 6 26 / 80 (32.50%) 32 3 / 80 (3.75%) 4 4 / 80 (5.00%) 4	0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 2 / 22 (9.09%) 2 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0	0 / 28 (0.00%) 0 0 / 28 (0.00%) 0 0 / 28 (0.00%) 0 5 / 28 (17.86%) 5 0 / 28 (0.00%) 0 0 / 28 (0.00%) 0
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all)	1 / 80 (1.25%) 2 1 / 80 (1.25%) 1	0 / 22 (0.00%) 0 0 / 22 (0.00%) 0	0 / 28 (0.00%) 0 0 / 28 (0.00%) 0
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	0 / 80 (0.00%) 0	0 / 22 (0.00%) 0	0 / 28 (0.00%) 0

Non-serious adverse events	Quadrivalent Influenza Vaccine: >60 years		
Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 20 (15.00%)		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
General disorders and administration site conditions Crying subjects affected / exposed occurrences (all) Injection Site Erythema subjects affected / exposed occurrences (all) Injection Site Induration subjects affected / exposed occurrences (all) Injection Site Pain subjects affected / exposed occurrences (all) Malaise subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0 1 / 20 (5.00%) 1 0 / 20 (0.00%) 0 1 / 20 (5.00%) 1 0 / 20 (0.00%) 0 0 / 20 (0.00%) 0		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0 0 / 20 (0.00%) 0		
Metabolism and nutrition disorders Decreased Appetite			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported