Clinical trial results:
Efficacy and Safety of a Novel Tetravalent Dengue Vaccine in Healthy Children and Adolescents Aged 9 to 16 Years in Latin America

Summary

EudraCT number	2014-001716-19
Trial protocol	Outside EU/EEA
Global end of trial date	05 March 2018

Results information

Result version number	v3 (current)
This version publication date	20 January 2023
First version publication date	02 August 2015
Version creation reason	• Correction of full data set Updated safety optional field

Trial information

Trial identification

Sponsor protocol code	CYD15

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01374516
WHO universal trial number (UTN)	U1111-1116-4986

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	11 October 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 March 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy of CYD dengue vaccine after 3 vaccinations (one each at 0, 6 and 12 months) in preventing symptomatic virologically-confirmed dengue cases, regardless of the severity, due to any of the four serotypes in children and adolescents aged 9 to 16 years at the time of inclusion.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were randomized and vaccinated in the study. Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment was also available on site in case of any immediate allergic reactions.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	08 June 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	72 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Colombia: 9743
Country: Number of subjects enrolled	Honduras: 2799
Country: Number of subjects enrolled	Brazil: 3548
Country: Number of subjects enrolled	Mexico: 3464
Country: Number of subjects enrolled	Puerto Rico: 1315
Worldwide total number of subjects	20869
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	9458
Adolescents (12-17 years)	11411
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study subjects were enrolled from 08 June 2011 to 16 March 2012 at 5 clinical centers in Brazil, 9 in Colombia, 1 in Honduras, 5 in Mexico, and 2 in Puerto Rico.

Pre-assignment

Screening details:

A total of 20869 subjects who met all of the inclusion and none of the exclusion criteria were enrolled and randomized in the study.

Period 1

Period 1 title	Vaccination Phase (Up to 25 Months)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Assessor

Blinding implementation details:

The observer-blind design was chosen since the products have different aspects and could be recognized. The person who performed vaccinations knew which product was administered while neither the subject nor the Investigator in charge of safety evaluation knew which product was injected. To maintain the blind and minimize any potential bias, the control group used the same route and schedule as the study vaccine.

Arms

Are arms mutually exclusive?	Yes
Arm title	CYD Dengue vaccine group

Arm description:

Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

Arm type	Experimental
Investigational medicinal product name	CYD Dengue vaccine
Investigational medicinal product code	323
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous, 3 injections. One each at 0, 6, and 12 months.

Arm title	Placebo group

Arm description:

Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

Arm type	Placebo
Investigational medicinal product name	Placebo (NaCl)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous, 3 injections. One each at 0, 6, and 12 months.

Number of subjects in period 1	CYD Dengue vaccine group	Placebo group
Started	13920	6949
Completed	13281	6640
Not completed	639	309
Consent withdrawn by subject	480	240
Adverse event, non-fatal	3	-
Serious adverse event	7	9
Lost to follow-up	106	46
Protocol deviation	43	14

Period 2

Period 2 title	Surveillance Expansion Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	CYD Dengue Vaccine Group

Arm description:

Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

Arm type	Experimental
Investigational medicinal product name	CYD Dengue vaccine
Investigational medicinal product code	323
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous, 3 injections. One each at 0, 6, and 12 months.

Arm title	Placebo Group

Arm description:

Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

Arm type	Placebo
Investigational medicinal product name	Placebo (NaCl)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous, 3 injections. One each at 0, 6, and 12 months.

Number of subjects in period 2	CYD Dengue Vaccine Group	Placebo Group
Started	13281	6640
Completed	10932	5387
Not completed	2349	1253
Consent withdrawn by subject	1870	986
Serious adverse event	20	5
Lost to follow-up	73	45
Protocol deviation	386	217

Baseline characteristics

Reporting groups	
Reporting group title	CYD Dengue vaccine group
Reporting group description:	
Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).	
Reporting group title	Placebo group
Reporting group description:	
Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).	

Reporting group values	CYD Dengue vaccine group	Placebo group	Total
Number of subjects	13920	6949	20869
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)	6307	3151	9458
Adolescents (12-17 years)	7613	3798	11411
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	12.5	12.5	
standard deviation	± 2.14	± 2.13	-
Gender categorical Units: Subjects			
Female	7048	3532	10580
Male	6872	3417	10289
Region of Enrollment Units: Subjects			
Colombia	6497	3246	9743
Brazil	2370	1178	3548
Mexico	2312	1152	3464
Honduras	1866	933	2799
Puerto Rico	875	440	1315

End points

End points reporting groups

Reporting group title	CYD Dengue vaccine group
Reporting group description:	
Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).	
Reporting group title	Placebo group
Reporting group description:	
Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).	
Reporting group title	CYD Dengue Vaccine Group
Reporting group description:	
Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).	
Reporting group title	Placebo Group
Reporting group description:	
Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).	

Primary: Number of Symptomatic Virologically Confirmed Dengue (VCD) Cases Due to Any Serotype During the Active Phase Post-dose 3 Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Symptomatic Virologically Confirmed Dengue (VCD) Cases Due to Any Serotype During the Active Phase Post-dose 3 Following Injection With Either CYD Dengue Vaccine or a Placebo
End point description:	
Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature >=38°C on at least 2 consecutive days) and confirmation of dengue virus infection by dengue reverse transcriptase polymerase chain reaction (RT-PCR) and/or dengue non-structural (NS) protein 1 antigen enzyme-linked immunosorbent assay (ELISA). Vaccine efficacy was defined as 1 minus the ratio of density incidence due to any serotype after at least 1 dose in the CYD Dengue Vaccine Group over the density incidence of the Placebo Group. Number of symptomatic VCD cases were assessed in the Per-Protocol Analysis Set for Efficacy, defined as subjects who had no protocol deviations.	
End point type	Primary
End point timeframe:	
28 days and up to 13 months post-injection 3	

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12574	6261		
Units: Cases				
number (not applicable)	176	221		

Statistical analyses

Statistical analysis title	Vaccine efficacy of the CYD dengue vaccine

Statistical analysis description:

The statistical methodology was based on the use of the two-sided 95 percent (%) confidence interval (CI) of the vaccine efficacy (expressed in %). The CI was calculated using the exact method conditional on the total number of cases in both groups (exact method by Breslow & Day). The vaccine efficacy of the CYD dengue vaccine was considered significant if the lower bound of its 95% CI was greater than 25%.

Comparison groups	CYD Dengue vaccine group v Placebo group
Number of subjects included in analysis	18835
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Vaccine Efficacy
Point estimate	60.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	52
upper limit	68

Secondary: Number of Symptomatic VCD Cases Due to Any Serotype During the Active Phase Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Symptomatic VCD Cases Due to Any Serotype During the Active Phase Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature >=38°C on at least 2 consecutive days) and confirmation of dengue virus infection by dengue RT-PCR and/or dengue NS 1 ELISA. Vaccine efficacy was defined as 1 minus the ratio of density incidence due to any serotype after at least 1 dose in the CYD Dengue Vaccine Group over the density incidence of the Placebo Group. Number of symptomatic VCD cases were assessed in the Full Analysis Set for Efficacy, which included all subjects who received at least 1 injection.

End point type	Secondary

End point timeframe:

Day 0 up to 13 months post-injection 3

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13914	6940		
Units: Cases				
number (not applicable)	277	385		

Statistical analyses

Statistical analysis title	Vaccine efficacy of the CYD dengue vaccine

Statistical analysis description:

The statistical methodology was based on the use of the two-sided 95% confidence interval (CI) of the

vaccine efficacy (expressed in %). The CI was calculated using the exact method conditional on the total number of cases in both groups (exact method by Breslow & Day). The vaccine efficacy of the CYD dengue vaccine was considered significant if the lower bound of its 95% CI was greater than 25%.

Comparison groups	CYD Dengue vaccine group v Placebo group
Number of subjects included in analysis	20854
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Vaccine Efficacy
Point estimate	64.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	58.7
upper limit	69.8

Secondary: Number of Symptomatic VCD Cases Due to Any Serotype Occurring 28 Days Post-dose 1 Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Symptomatic VCD Cases Due to Any Serotype Occurring 28 Days Post-dose 1 Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature >= 38°C on at least 2 consecutive days) and confirmation of dengue virus infection by dengue RT-PCR and/or dengue NS 1 ELISA. Vaccine efficacy was defined as 1 minus the ratio of density incidence due to any serotype after at least 1 dose in the CYD Dengue Vaccine Group over the density incidence of the Placebo Group. Number of symptomatic VCD cases were assessed in the Full Analysis Set for Efficacy, which included subjects who received at least 1 dose of study vaccine.

End point type	Secondary

End point timeframe:

28 days post-injection 1 and up to 13 months post-injection 3

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13914	6940		
Units: Cases				
number (not applicable)	273	380		

Statistical analyses

Statistical analysis title	Vaccine efficacy of CYD dengue vaccine

Statistical analysis description:

The statistical methodology was based on the use of the two-sided 95% CI of the vaccine efficacy (expressed in %) calculated using the exact method conditional on the total number of cases in both groups.

Comparison groups	CYD Dengue vaccine group v Placebo group

Number of subjects included in analysis	20854
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Vaccine Efficacy
Point estimate	64.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	58.7
upper limit	69.9

Secondary: Number of Symptomatic VCD Cases Due to Any Serotype Post-dose 2 Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Symptomatic VCD Cases Due to Any Serotype Post-dose 2 Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature >= 38°C on at least 2 consecutive days) and confirmation of dengue virus infection by dengue RT-PCR and/or dengue NS 1 ELISA. Vaccine efficacy was defined as 1 minus the ratio of density incidence due to any serotype after at least 1 dose in the CYD Dengue Vaccine Group over the density incidence of the Placebo Group. Number of symptomatic VCD cases were assessed in the Other Efficacy Analysis Set, which included subjects who received at least 2 doses of study vaccine.

End point type	Secondary

End point timeframe:

28 days post-injection 2 and up to 13 months post-injection 3

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13506	6765		
Units: Cases				
number (not applicable)	236	306		

Statistical analyses

Statistical analysis title	Vaccine efficacy of the CYD dengue vaccine

Statistical analysis description:

The statistical methodology was based on the use of the two-sided 95% CI of the vaccine efficacy (expressed in %) calculated using the exact method conditional on the total number of cases in both groups.

Comparison groups	CYD Dengue vaccine group v Placebo group

Number of subjects included in analysis	20271
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Vaccine Efficacy
Point estimate	61.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.7
upper limit	68

Secondary: Number of Symptomatic VCD Cases Meeting World Health Organization (WHO) Criteria Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Symptomatic VCD Cases Meeting World Health Organization (WHO) Criteria Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

Dengue hemorrhagic fever (DHF) cases were defined as number of subjects with at least one symptomatic VCD episode meeting the 1997 WHO criteria (a)Fever: acute onset, high (>= 38°C) and continuous, lasting 2 to 7days and (b)any of the pre-listed hemorrhagic manifestations and laboratory findings of thrombocytopenia (platelet <=100 x 109/L) and plasma leakage as shown by hemoconcentration (hematocrit increased by 20% or more) or pleural effusion (seen on Chest X-Ray [CXR]) and/or ascites and/ or hypoalbuminemia. DHF was graded as follows: Grade I: Fever accompanied by non-specific constitutional symptoms; Grade II: Spontaneous bleeding in addition to the manifestations of Grade I subjects, usually in the form of skin and/or other hemorrhage. Number of WHO dengue hemorrhagic fever cases were assessed in the Safety Analysis Set, which included all subjects who received at least one dose of study vaccine. Here, 'subjects analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 0 to the end of study (up to 72 months)

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12809	6380		
Units: Cases				
number (not applicable)				
Due to Any of the 4 Serotypes: Any Grade	7	15		
Due to Any of the 4 Serotypes: Grade I	0	2		
Due to Any of the 4 Serotypes: Grade II	7	13		
Due to Any of the 4 Serotypes: Grade III	0	0		
Due to Any of the 4 Serotypes: Grade IV	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Symptomatic VCD Cases Meeting WHO Criteria During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Symptomatic VCD Cases Meeting WHO Criteria During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

The 1997 WHO criteria: a)Fever: acute onset, high (>=38°C) and continuous, for 2 to 7days and (b)any of the following: thrombocytopenia (platelet<=100 x 109/L) and plasma leakage as shown by hematocrit increased by 20% or more or pleural effusion and/or ascites and/or hypoalbuminemia. DHF was graded as follows: Grade I:Fever accompanied by non-specific constitutional symptoms; Grade II:Spontaneous bleeding in addition to the manifestations of Grade I subject, usually in the form of skin and/or other hemorrhages; Grade III:Circulatory failure manifested by rapid and weak pulse, narrowing of pulse pressure (20mmHg or less) or hypotension, with the presence of cold clammy skin and restlessness; and Grade IV: Profound shock with undetectable blood pressure and pulse. Number of WHO DHF cases were assessed in the Full Analysis Set for Surveillance Expansion Period, which included all subjects who received at least 1 injection and accepted to be included in the Surveillance Expansion Period.

End point type	Secondary

End point timeframe:

From consent to participate in the Surveillance Expansion Period to the end of study (up to 72 months)

End point values	CYD Dengue Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11063	5430		
Units: Cases				
number (not applicable)				
Due to Any of the 4 Serotypes: Any Grade	2	0		
Due to Any of the 4 Serotypes: Grade I	0	0		
Due to Any of the 4 Serotypes: Grade II	2	0		
Due to Any of the 4 Serotypes: Grade III	0	0		
Due to Any of the 4 Serotypes: Grade IV	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Hospitalized VCD Cases Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Hospitalized VCD Cases Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

Hospitalized VCD cases were defined as VCD confirmed by dengue RT–PCR and/or dengue NS 1 ELISA in subjects with acute febrile illness (temperature >=38°C on at least 2 consecutive days) requiring hospitalization. Number of hospitalized dengue hemorrhagic fever cases were assessed in the Safety Analysis Set. Here, 'subjects analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 0 up to the end of study (up to 72 months)

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12809	6380		
Units: Cases				
number (not applicable)	46	71		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Hospitalized VCD Cases During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Hospitalized VCD Cases During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

Hospitalized VCD cases were defined as VCD confirmed by dengue RT–PCR and/or dengue NS 1 ELISA in subjects with acute febrile illness (temperature >=38°C on at least 2 consecutive days) requiring hospitalization. Analysis was performed in the Safety Analysis Set.

End point type	Secondary

End point timeframe:

From consent to participate in the Surveillance Expansion Period to the end of study (up to 72 months)

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13915	6939		
Units: Cases				
number (not applicable)	5	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Clinically Severe VCD Cases Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Clinically Severe VCD Cases Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

The Severity of VCD cases was assessed by an Independent Data monitoring Committee (IDMC) based on medical review of cases and any of following criteria: 1)Platelet count <=100000/µl and bleeding (tourniquet, petechiae or any bleeding) plus plasma leakage 2)Shock (pulse pressure <=20mmHg in child, or hypotension [<=90mmHg] with tachycardia, weak pulse and poor perfusion) 3) Bleeding requiring blood transfusion 4)Encephalopathy i.e. unconsciousness or poor conscious state. Poor conscious state or unconsciousness must be supported by Glasgow Coma Scale (GCS) score 5)Liver impairment (AST >1000IU/L or prothrombin time [PT] International normalized ratio [INR] >1.5) excluding other causes of viral hepatitis 6) Impaired kidney function (serum creatinine >= 1.5mg/dL) 7) Myocarditis, pericarditis or clinical heart failure supported by CXR, echocardiography, ECG or cardiac enzymes. Analysis was performed in Safety Analysis Set. Here, 'subjects analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 0 to the end of study (up to 72 months)

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12809	6380		
Units: Cases				
number (not applicable)	9	16		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Clinically Severe VCD Cases During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Clinically Severe VCD Cases During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

The severity of VCD cases was assessed by an IDMC based on a medical review of cases and any of the following criteria:-1) Platelet count <=100000 /µl and bleeding (tourniquet, petechiae or any bleeding) plus plasma leakage 2) Shock (pulse pressure <= 20 mmHg in a child, or hypotension [<= 90 mmHg] with tachycardia, weak pulse and poor perfusion) 3) Bleeding requiring blood transfusion 4) Encephalopathy i.e. Unconsciousness or poor conscious state or fitting not attributable to simple febrile convulsion or focal neurological signs. Poor conscious state or unconsciousness must be supported by GCS score 5) Liver impairment (AST >1000 IU/L or PT INR >1.5) excluding other causes of viral hepatitis 6) Impaired kidney function (serum creatinine >= 1.5 mg/dL) 7) Myocarditis, pericarditis or clinical heart failure supported by CXR, echocardiography, ECG or cardiac enzymes. Number of clinically severe VCD cases were assessed in the Full Analysis Set for Surveillance Expansion Period.

End point type	Secondary

End point timeframe:

From consent to participate in the Surveillance Expansion Period to the end of study (up to 72 months)

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11061	5431		
Units: Cases				
number (not applicable)	42	34		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Titers >=10 1/Dil Against Each Dengue Virus Serotype Before and Following Injection (Inj.) With CYD Dengue Vaccine or Placebo

End point title	Percentage of Subjects With Antibody Titers >=10 1/Dil Against Each Dengue Virus Serotype Before and Following Injection (Inj.) With CYD Dengue Vaccine or Placebo

End point description:

Dengue neutralizing antibody levels against each of the 4 dengue virus serotypes (parental strains) were measured by the plaque reduction neutralization test (PRNT) in a pre-defined subset of subjects. Antibody titers against each dengue virus serotype strain were assessed in Full Analysis Set for Immunogenicity (FASI), which included a subset of subjects who received at least one dose of vaccine and had a blood sample drawn and result available after the dose. Here, 'n'= subjects with available data for each specified category.

End point type	Secondary

End point timeframe:

Pre-injection 1, 28 days post Injections 2 and 3, 13 months and 60 months post-injection 3

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1301	643		
Units: Percentage of subjects				
number (not applicable)				
Dengue virus Serotype 1: Pre-Inj.1 (n=1297,641)	72.8	70.5		
Dengue virus Serotype 1: Post-Inj. 2 (n=1296,638)	92.7	71.8		
Dengue virus Serotype 1: Post-Inj. 3 (n=1291,640)	94.9	74.2		
Dengue virus Serotype 1;1yr Post-Inj.3(n=1261,629)	85.6	73.6		
Dengue virus Serotype 1;5yr Post-Inj.3(n=1038,508)	90.0	81.1		

Dengue virus Serotype 2; Pre-Inj. 1 (n=1299,640)	76.1	73.8		
Dengue virus Serotype 2; Post-Inj. 2 (n=1297,639)	97.5	75.1		
Dengue virus Serotype 2; Post-Inj. 3 (n=1291,640)	98.5	77.2		
Dengue virus Serotype 2;1yr Post-Inj.3(n=1264,629)	94.1	78.9		
Dengue virus Serotype 2;5yr Post-Inj.3(n=1038,508)	93.5	83.1		
Dengue virus Serotype 3; Pre-Inj. 1 (n=1300,639)	76.5	73.6		
Dengue virus Serotype 3; Post-Inj. 2 (n=1297,639)	98.5	75.7		
Dengue virus Serotype 3; Post-Inj. 3 (n=1291,640)	98.4	78.0		
Dengue virus Serotype 3;1yr Post-Inj.3(n=1265,629)	92.7	76.2		
Dengue virus Serotype 3;5yr Post-Inj.3(n=1038,508)	95.4	82.7		
Dengue virus Serotype 4; Pre-Inj. 1(n=1297,640)	68.2	65.0		
Dengue virus Serotype 4; Post-Inj. 2 (n=1295,637)	96.9	67.0		
Dengue virus Serotype 4; Post-Inj. 3 (n=1291,640)	98.1	68.9		
Dengue virus Serotype 4;1yr Post-Inj.3(n=1265,625)	94.9	69.0		
Dengue virus Serotype 4;5yr Post-Inj.3(n=1038,508)	96.3	78.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Each Dengue Virus Serotype Before and Following Injection With Either CYD Dengue Tetravalent Vaccine or a Placebo

End point title	Geometric Mean Titers of Antibodies Against Each Dengue Virus Serotype Before and Following Injection With Either CYD Dengue Tetravalent Vaccine or a Placebo

End point description:

Geometric mean titers for each of the 4 dengue virus serotypes (parental strains) were assessed using the plaque reduction neutralization test (PRNT) in a pre-defined subset of subjects. Antibody titers against each dengue virus serotype strain were assessed in FASI, which included a subset of subjects who received at least one dose of vaccine and had a blood sample drawn and result available after the dose. Here, 'n' = subjects with available data for each specified category.

End point type	Secondary

End point timeframe:

Pre-injection 1, 28 days post Injections 2 and 3, 13 months and 60 months post-injection 3

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1301	643		
Units: Titers (1/dilution)				
geometric mean (confidence interval 95%)				
Dengue virus Serotype 1: Pre-Inj.1 (n=1297,641)	128 (112 to 145)	119 (98.7 to 142)		
Dengue virus Serotype 1: Post-Inj. 2 (n=1296,638)	458 (406 to 517)	128 (106 to 154)		
Dengue virus Serotype 1: Post-Inj. 3 (n=1291,640)	395 (353 to 441)	121 (101 to 145)		
Dengue virus Serotype 1;1yr Post-Inj.3(n=1261,629)	266 (234 to 302)	146 (121 to 176)		
Dengue virus Serotype 1;5yr Post-Inj.3(n=1038,508)	284 (252 to 321)	210 (172 to 255)		
Dengue virus Serotype 2; Pre-Inj. 1 (n=1299,640)	138 (123 to 156)	115 (97.2 to 136)		
Dengue virus Serotype 2; Post-Inj. 2 (n=1297,639)	622 (566 to 684)	124 (104 to 148)		
Dengue virus Serotype 2; Post-Inj. 3 (n=1291,640)	574 (528 to 624)	129 (109 to 152)		
Dengue virus Serotype 2;1yr Post-Inj.3(n=1264,629)	371 (336 to 409)	145 (122 to 173)		
Dengue virus Serotype 2;5yr Post-Inj.3(n=1038,508)	297 (269 to 328)	201 (168 to 242)		
Dengue virus Serotype 3; Pre-Inj. 1 (n=1300,639)	121 (108 to 136)	114 (95.9 to 136)		
Dengue virus Serotype 3; Post-Inj. 2 (n=1297,639)	556 (506 to 610)	117 (98.3 to 139)		
Dengue virus Serotype 3; Post-Inj. 3 (n=1291,640)	508 (465 to 555)	124 (105 to 147)		
Dengue virus Serotype 3;1yr Post-Inj.3(n=1265,629)	292 (263 to 325)	137 (114 to 165)		
Dengue virus Serotype 3;5yr Post-Inj.3(n=1038,508)	346 (313 to 383)	224 (185 to 271)		
Dengue virus Serotype 4; Pre-Inj. 1(n=1297,640)	43.6 (39.6 to 48.0)	39.0 (33.9 to 44.7)		
Dengue virus Serotype 4; Post-Inj. 2 (n=1295,637)	261 (242 to 281)	40.9 (35.5 to 47.0)		
Dengue virus Serotype 4; Post-Inj. 3 (n=1291,640)	241 (226 to 258)	44.3 (38.6 to 50.8)		
Dengue virus Serotype 4;1yr Post-Inj.3(n=1265,625)	174 (161 to 188)	51.5 (44.3 to 59.8)		
Dengue virus Serotype 4;5yr Post-Inj.3(n=1038,508)	144 (134 to 156)	73.6 (63.4 to 85.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Injection Site Reactions Following Any and Each Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Subjects With Solicited Injection Site Reactions Following Any and Each Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

Solicited injection site reactions: Pain, Erythema, and Swelling. Grade 3 reactions (9-11 years): Pain: incapacitating, unable to perform usual activities; Erythema and Swelling, >= 50 mm. Grade 3 Solicited injection site reactions (12-16 years): Pain: significant, prevents daily activity; Erythema and Swelling, >100 mm. Solicited injection site reactions were assessed in a subset of the Safety Analysis Set, which included all subjects who received at least one dose of study vaccine and who were evaluated for reactogenicity. Here, 'number analyzed' = subjects with available data for specified category.

End point type	Secondary

End point timeframe:

Within 7 days after each and any injection

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1333	664		
Units: Subjects				
number (not applicable)				
Injection-site Pain (Post any inj.) (n=1328,658)	650	270		
Injection-site Erythema(Post-any inj.)(n=1328,658)	83	44		
Injection-site Swelling(Post-any inj.)(n=1328,658)	77	27		
Injection-site Pain (Post-inj. 1)(n=1326,657)	430	173		
Grade 3 Inj.-site Pain (Post-inj.1)(n=1326,657)	11	6		
Injection-site Erythema (Post-inj.1)(n=1326,656)	55	31		
Grade3 Inj.-site Erythema (Post-inj.1)(n=1326,656)	0	1		
Injection-site Swelling (Post-inj. 1)(n=1326,656)	47	18		
Grade3 Inj.-site Swelling (Post-inj.1)(n=1326,656)	0	1		
Injection-site Pain (Post-inj. 2)(n=1297,639)	332	105		
Grade3 Injection-site Pain(Post-inj.2)(n=1297,639)	7	0		
Injection-site Erythema (Post-inj.2) (n=1296,639)	25	11		
Grade3 Inj.-site Erythema (Post-inj.2)(n=1296,639)	1	0		
Injection-site Swelling (Post-inj. 2)(n=1296,639)	25	6		
Grade3 Inj.-site Swelling (Post-inj.2)(n=1296,639)	0	0		
Injection-site Pain (Post-inj. 3)(n=1279,630)	288	104		
Grade 3 Inj-site Pain (Post-inj. 3)(n=1279,630)	11	2		
Injection-site Erythema (Post-inj. 3)(n=1278,631)	19	10		
Grade3 Inj.-site Erythema (Post-inj.3)(n=1278,631)	0	0		
Injection-site Swelling (Post-inj. 3) (n=1279,631)	20	8		

Grade3 Inj.-site Swelling (Postinj.3) (n=1279,631)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Systemic Reactions Following Any and Each Injection With Either CYD Dengue Vaccine or a Placebo

End point title	Number of Subjects With Solicited Systemic Reactions Following Any and Each Injection With Either CYD Dengue Vaccine or a Placebo

End point description:

Solicited systemic reactions: Fever (Temperature), Headache, Malaise, Myalgia, and Asthenia. Grade 3 reactions: Fever: >= 39°C; Headache, Malaise, Myalgia, and Asthenia: significant, prevents daily activity. Solicited systemic reactions were assessed in a subset of the Safety Analysis Set, which included all subjects who received at least one dose of study vaccine and who were evaluated for reactogenecity. Here, 'n' = subjects with available data for specified category.

End point type	Secondary

End point timeframe:

Within 14 days after each and any injection

End point values	CYD Dengue vaccine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1333	664		
Units: Subjects				
number (not applicable)				
Fever (Post any inj.) (n=1318,654)	220	123		
Headache (Post any inj.) (n=1328,659)	727	379		
Malaise (Post any inj.) (n=1328,659)	536	261		
Myalgia (Post any inj.) (n=1328,659)	576	267		
Asthenia (Post any inj.) (n=1328,659)	496	251		
Fever (Post-inj. 1) (n=1264,635)	86	42		
Grade 3 Fever (Post-inj. 1) (n=1264,635)	21	7		
Headache (Post-inj. 1) (n=1324,657)	528	273		
Grade 3 Headache (Post-inj. 1) (n=1324,657)	67	27		
Malaise (Post-inj. 1) (n=1323,657)	324	170		
Grade 3 Malaise (Post-inj. 1) (n=1323,657)	32	15		
Myalgia (Post-inj. 1) (n=1323,657)	386	180		
Grade 3 Myalgia (Post-inj. 1) (n=1323,657)	29	10		
Asthenia (Post-inj. 1) (n=1323,657)	326	148		
Grade 3 Asthenia (Post-inj. 1) (n=1323,657)	36	17		
Fever (Post-inj. 2) (n=1228,594)	72	42		

Grade 3 Fever (Post-inj. 2) (n=1228,594)	10	7		
Headache (Post-inj. 2) (n=1297,639)	386	182		
Grade 3 Headache (Post-inj. 2) (n=1297,639)	27	15		
Malaise (Post-inj. 2) (n=1298,639)	270	106		
Grade 3 Malaise (Post-inj. 2) (n=1298,639)	17	8		
Myalgia (Post-inj. 2) (n=1298,639)	273	101		
Grade 3 Myalgia (Post-inj. 2) (n=1298,639)	21	5		
Asthenia (Post-inj. 2) (n=1298,639)	231	105		
Grade 3 Asthenia (Post-inj. 2) (n=1298,639)	24	7		
Fever (Post-inj. 3) (n=1215,597)	89	52		
Grade 3 Fever (Post-inj. 3) (n=1215,597)	13	5		
Headache (Post-inj. 3) (n=1277,631)	378	158		
Grade 3 Headache (Post-inj. 3) (n=1277,631)	33	12		
Malaise (Post-inj. 3) (n=1277,631)	246	96		
Grade 3 Malaise (Post-inj. 3) (n=1277,631)	18	7		
Myalgia (Post-inj. 3) (n=1277,631)	255	116		
Grade 3 Myalgia (Post-inj. 3) (n=1277,631)	19	5		
Asthenia (Post-inj. 3) (n=1277,631)	208	110		
Grade 3 Asthenia (Post-inj. 3) (n=1277,631)	17	8		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Unsolicited adverse event (AE) data: collected from Day 0 (post-vaccination) up to 28 days after each vaccination. Solicited Reaction (SR) data: within 7 and 14 days after vaccination. Serious adverse event (SAE) data was collected throughout the study.

Adverse event reporting additional description:

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

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.0

Reporting groups

Reporting group title	CYD Dengue Vaccine Group

Reporting group description:

Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months.

Reporting group title	Placebo Group

Reporting group description:

subjects received 3 doses of placebo vaccine; one each at 0, 6, and 12 months.

Serious adverse events	CYD Dengue Vaccine Group	Placebo Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1765 / 13915 (12.68%)	911 / 6939 (13.13%)	
number of deaths (all causes)	42	27	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Hydatidiform Mole			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Ovarian Tumour			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Pancreatic Neoplasm			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Giant Cell Tumour			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Sarcoma			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain Neoplasm Malignant			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrosarcoma			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Myeloid Leukaemia			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Desmoid Tumour			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibroadenoma Of Breast			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma Of Skin			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hodgkin's Disease			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondroma			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoma			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteosarcoma Metastatic			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Osteosarcoma Recurrent			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ovarian Adenoma			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Germ Cell Teratoma Benign			

subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary Tumour Benign			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Cancer			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Leiomyoma			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertensive Crisis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secondary Hypertension			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abortion Induced			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Induced Complete			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Caesarean Section			

subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity Surgery			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scoliosis Surgery			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgery			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical Hernia Repair			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abnormal Product Of Conception			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion			
subjects affected / exposed	14 / 13915 (0.10%)	6 / 6939 (0.09%)	
occurrences causally related to treatment / all	0 / 14	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Complete			

subjects affected / exposed	9 / 13915 (0.06%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Complicated			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Incomplete			
subjects affected / exposed	22 / 13915 (0.16%)	9 / 6939 (0.13%)	
occurrences causally related to treatment / all	0 / 22	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Incomplete Complicated			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Missed			
subjects affected / exposed	3 / 13915 (0.02%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Of Ectopic Pregnancy			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Spontaneous			
subjects affected / exposed	48 / 13915 (0.34%)	30 / 6939 (0.43%)	
occurrences causally related to treatment / all	0 / 51	0 / 34	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Spontaneous Complete			
subjects affected / exposed	8 / 13915 (0.06%)	6 / 6939 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Spontaneous Complicated			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Spontaneous Incomplete			
subjects affected / exposed	16 / 13915 (0.11%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 16	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Spontaneous Incomplete Complicated			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Threatened			
subjects affected / exposed	14 / 13915 (0.10%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 14	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amniorrhexis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Antepartum Haemorrhage			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blighted Ovum			
subjects affected / exposed	11 / 13915 (0.08%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 11	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cephalo-Pelvic Disproportion			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Incompetence			

subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication Of Delivery			
subjects affected / exposed	4 / 13915 (0.03%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delivery			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eclampsia			
subjects affected / exposed	5 / 13915 (0.04%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ectopic Pregnancy			
subjects affected / exposed	3 / 13915 (0.02%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failed Induction Of Labour			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
False Labour			
subjects affected / exposed	39 / 13915 (0.28%)	14 / 6939 (0.20%)	
occurrences causally related to treatment / all	0 / 45	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foetal Distress Syndrome			
subjects affected / exposed	1 / 13915 (0.01%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gestational Hypertension			

subjects affected / exposed	12 / 13915 (0.09%)	7 / 6939 (0.10%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hellp Syndrome			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
High Risk Pregnancy			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperemesis Gravidarum			
subjects affected / exposed	3 / 13915 (0.02%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-Uterine Death			
subjects affected / exposed	1 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intrapartum Haemorrhage			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oligohydramnios			
subjects affected / exposed	12 / 13915 (0.09%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 12	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Placental Insufficiency			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpartum Haemorrhage			

subjects affected / exposed	8 / 13915 (0.06%)	5 / 6939 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pre-Eclampsia			
subjects affected / exposed	34 / 13915 (0.24%)	23 / 6939 (0.33%)	
occurrences causally related to treatment / all	0 / 35	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature Baby			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature Delivery			
subjects affected / exposed	6 / 13915 (0.04%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature Labour			
subjects affected / exposed	17 / 13915 (0.12%)	6 / 6939 (0.09%)	
occurrences causally related to treatment / all	0 / 17	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature Rupture Of Membranes			
subjects affected / exposed	13 / 13915 (0.09%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 13	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature Separation Of Placenta			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prolonged Labour			
subjects affected / exposed	1 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Puerperal Pyrexia			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retained Placenta Or Membranes			
subjects affected / exposed	2 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retained Products Of Conception			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ruptured Ectopic Pregnancy			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stillbirth			
subjects affected / exposed	6 / 13915 (0.04%)	5 / 6939 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Threatened Labour			
subjects affected / exposed	7 / 13915 (0.05%)	9 / 6939 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Catheter Site Phlebitis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Device Intolerance			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Discomfort			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drowning			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Malaise			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical Device Complication			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	9 / 13915 (0.06%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 9	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Inflammation			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden Death			

subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic Reaction			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Antiphospholipid Syndrome			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Hypersensitivity			
subjects affected / exposed	1 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food Allergy			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Physical Assault			
subjects affected / exposed	9 / 13915 (0.06%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Sexual Abuse			
subjects affected / exposed	7 / 13915 (0.05%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance Use			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Victim Of Crime			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Victim Of Homicide			
subjects affected / exposed	5 / 13915 (0.04%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 5	0 / 1	
Victim Of Sexual Abuse			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bartholinitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Breast Disorder			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Mass			
subjects affected / exposed	4 / 13915 (0.03%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Pain			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coital Bleeding			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysfunctional Uterine Bleeding			
subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysmenorrhoea			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometriosis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female Genital Tract Fistula			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecomastia			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematocolpos			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematosalpinx			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic Ovarian Cyst			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cyst			
subjects affected / exposed	7 / 13915 (0.05%)	5 / 6939 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cyst Ruptured			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Torsion			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovulation Pain			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic Pain			
subjects affected / exposed	3 / 13915 (0.02%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycystic Ovaries			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retrograde Menstruation			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular Disorder			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular Torsion			
subjects affected / exposed	12 / 13915 (0.09%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 12	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Cyst			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Haemorrhage			

subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal Haemorrhage			
subjects affected / exposed	3 / 13915 (0.02%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicocele			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval Haematoma			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute Respiratory Failure			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenoidal Hypertrophy			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alveolitis Allergic			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			

subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Aspiration			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma			
subjects affected / exposed	19 / 13915 (0.14%)	17 / 6939 (0.24%)	
occurrences causally related to treatment / all	1 / 24	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthmatic Crisis			
subjects affected / exposed	12 / 13915 (0.09%)	7 / 6939 (0.10%)	
occurrences causally related to treatment / all	0 / 14	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial Obstruction			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Septum Deviation			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Turbinate Hypertrophy			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal Pain			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Artery Stenosis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Oedema			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory Tract Haemorrhage			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status Asthmaticus			

subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillar Cyst			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillar Hypertrophy			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Abnormal Behaviour			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Psychosis			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Stress Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjustment Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aggression			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorexia Nervosa			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar I Disorder			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar Disorder			
subjects affected / exposed	2 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed Suicide			
subjects affected / exposed	2 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Conduct Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion Disorder			
subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dependence			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			

subjects affected / exposed	18 / 13915 (0.13%)	9 / 6939 (0.13%)	
occurrences causally related to treatment / all	0 / 18	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression Suicidal			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dissociative Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Abuse			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Dependence			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional Drug Misuse			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional Self-Injury			
subjects affected / exposed	6 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent Explosive Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major Depression			

subjects affected / exposed	6 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obsessive Rumination			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			
subjects affected / exposed	1 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia, Undifferentiated Type			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatoform Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance Abuse			
subjects affected / exposed	14 / 13915 (0.10%)	9 / 6939 (0.13%)	
occurrences causally related to treatment / all	0 / 15	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal Ideation			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide Attempt			

subjects affected / exposed	19 / 13915 (0.14%)	8 / 6939 (0.12%)	
occurrences causally related to treatment / all	0 / 19	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Autoimmune Hepatitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stone			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	7 / 13915 (0.05%)	6 / 6939 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Acute			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Chronic			
subjects affected / exposed	3 / 13915 (0.02%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	9 / 13915 (0.06%)	13 / 6939 (0.19%)	
occurrences causally related to treatment / all	0 / 9	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis Of Pregnancy			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Disorder			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis Acute			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis Toxic			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocholecystis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Investigation			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal Injury			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Accident			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident At Home			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident At Work			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum Fracture			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse Event Following Immunisation			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Poisoning			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal Bite			
subjects affected / exposed	3 / 13915 (0.02%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle Fracture			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod Sting			

subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Avulsion Fracture			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns Second Degree			
subjects affected / exposed	6 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns Third Degree			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical Poisoning			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Injury			
subjects affected / exposed	3 / 13915 (0.02%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Clavicle Fracture			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endotracheal Intubation Complication			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiphyseal Fracture			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Injury			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Penetration			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face Injury			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial Bones Fracture			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	28 / 13915 (0.20%)	11 / 6939 (0.16%)	
occurrences causally related to treatment / all	0 / 28	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Femur Fracture			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula Fracture			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot Fracture			

subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm Fracture			
subjects affected / exposed	21 / 13915 (0.15%)	7 / 6939 (0.10%)	
occurrences causally related to treatment / all	0 / 21	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign Body			
subjects affected / exposed	1 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign Body In Eye			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital Injury			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun Shot Wound			
subjects affected / exposed	24 / 13915 (0.17%)	15 / 6939 (0.22%)	
occurrences causally related to treatment / all	0 / 24	0 / 15	
deaths causally related to treatment / all	0 / 12	0 / 9	
Hand Fracture			
subjects affected / exposed	5 / 13915 (0.04%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head Injury			
subjects affected / exposed	16 / 13915 (0.11%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 17	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Humerus Fracture			

subjects affected / exposed	6 / 13915 (0.04%)	5 / 6939 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional Overdose			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Dislocation			
subjects affected / exposed	3 / 13915 (0.02%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Injury			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Crushing Injury			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Injury			
subjects affected / exposed	4 / 13915 (0.03%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Traumatic Amputation			
subjects affected / exposed	4 / 13915 (0.03%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Limb Fracture			

subjects affected / exposed	3 / 13915 (0.02%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus Lesion			
subjects affected / exposed	3 / 13915 (0.02%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Fractures			
subjects affected / exposed	6 / 13915 (0.04%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Injuries			
subjects affected / exposed	12 / 13915 (0.09%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 12	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Muscle Injury			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve Injury			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open Wound			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal Laceration			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax Traumatic			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning Deliberate			
subjects affected / exposed	15 / 13915 (0.11%)	10 / 6939 (0.14%)	
occurrences causally related to treatment / all	0 / 16	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 0	
Post Procedural Haemorrhage			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-Traumatic Pain			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Wound Complication			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural Complication			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius Fracture			

subjects affected / exposed	8 / 13915 (0.06%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road Traffic Accident			
subjects affected / exposed	108 / 13915 (0.78%)	39 / 6939 (0.56%)	
occurrences causally related to treatment / all	0 / 109	0 / 39	
deaths causally related to treatment / all	0 / 5	0 / 5	
Skull Fracture			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Injury			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Cord Injury			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Cord Injury Cervical			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sports Injury			
subjects affected / exposed	8 / 13915 (0.06%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stab Wound			
subjects affected / exposed	5 / 13915 (0.04%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Injury			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Rupture			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular Injury			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal Burn			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia Fracture			
subjects affected / exposed	5 / 13915 (0.04%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity To Various Agents			
subjects affected / exposed	7 / 13915 (0.05%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Traumatic Brain Injury			
subjects affected / exposed	5 / 13915 (0.04%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Traumatic Fracture			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna Fracture			

subjects affected / exposed	3 / 13915 (0.02%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulnar Nerve Injury			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Limb Fracture			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Access Complication			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist Fracture			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous Malformation			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Septal Defect			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryptorchism			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hereditary Spherocytosis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	0 / 13915 (0.00%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sickle Cell Trait			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wolff-Parkinson-White Syndrome			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Acute Disseminated Encephalomyelitis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Polyneuropathy			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Arachnoid Cyst			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atonic Seizures			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar Syndrome			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complicated Migraine			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	21 / 13915 (0.15%)	10 / 6939 (0.14%)	
occurrences causally related to treatment / all	0 / 31	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Epilepsy			
subjects affected / exposed	26 / 13915 (0.19%)	8 / 6939 (0.12%)	
occurrences causally related to treatment / all	0 / 86	0 / 27	
deaths causally related to treatment / all	0 / 1	0 / 0	
Grand Mal Convulsion			

subjects affected / exposed	2 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre Syndrome			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage Intracranial			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhagic Cerebral Infarction			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	2 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersomnia			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Encephalopathy			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic Generalised Epilepsy			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial Aneurysm			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine With Aura			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine Without Aura			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy Peripheral			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial Seizures			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-Traumatic Headache			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status Epilepticus			

subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status Migrainosus			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	6 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viith Nerve Paralysis			
subjects affected / exposed	5 / 13915 (0.04%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 13915 (0.00%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Of Pregnancy			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aplastic Anaemia			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic Anaemia			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic Thrombocytopenic Purpura			

subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			
subjects affected / exposed	7 / 13915 (0.05%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoid Tissue Hyperplasia			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenic Purpura			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Tympanic Membrane Perforation			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Keratoconus			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal Detachment			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual Impairment			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Adhesions			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain			
subjects affected / exposed	26 / 13915 (0.19%)	9 / 6939 (0.13%)	
occurrences causally related to treatment / all	0 / 26	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Lower			
subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Upper			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Abdomen			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Haemorrhage			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	3 / 13915 (0.02%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	5 / 13915 (0.04%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			

subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food Poisoning			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	12 / 13915 (0.09%)	5 / 6939 (0.07%)	
occurrences causally related to treatment / all	0 / 13	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis Haemorrhagic			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingivitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia, Obstructive			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Functional Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Obstruction			
subjects affected / exposed	1 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable Bowel Syndrome			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malocclusion			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Acute			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic Ulcer			

subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical Hernia			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical Hernia, Obstructive			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices Oesophageal			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting In Pregnancy			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis Atopic			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema Nodosum			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Henoch-Schonlein Purpura			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic Scar			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical Urticaria			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash Erythematous			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Fissures			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous Nodule			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	4 / 13915 (0.03%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Calculus Ureteric			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus Urethral			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus Urinary			
subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis Haemorrhagic			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lupus Nephritis			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nephritic Syndrome			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	15 / 13915 (0.11%)	5 / 6939 (0.07%)	
occurrences causally related to treatment / all	0 / 15	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Streptococcal Glomerulonephritis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Colic			
subjects affected / exposed	2 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Tubular Necrosis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial Nephritis			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urogenital Haemorrhage			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Basedow's Disease			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothalamo-Pituitary Disorder			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Ankle Deformity			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	4 / 13915 (0.03%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiphysiolysis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Juvenile Arthritis			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee Deformity			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopathy			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological Fracture			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatic Fever			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid Arthritis			

subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sacroiliitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial Cyst			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic Lupus Erythematosus			
subjects affected / exposed	2 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal Abscess			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Infected			
subjects affected / exposed	1 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Limb			
subjects affected / exposed	6 / 13915 (0.04%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Neck			

subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Of Salivary Gland			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Oral			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Sinusitis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Tonsillitis			
subjects affected / exposed	1 / 13915 (0.01%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoiditis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amniotic Cavity Infection			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amoebiasis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amoebic Dysentery			

subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Abscess			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anogenital Warts			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	261 / 13915 (1.88%)	138 / 6939 (1.99%)	
occurrences causally related to treatment / all	0 / 261	0 / 138	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis Perforated			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis Bacterial			
subjects affected / exposed	3 / 13915 (0.02%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis Infective			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asymptomatic Hiv Infection			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial Infection			

subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bartholin's Abscess			
subjects affected / exposed	2 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Abscess			
subjects affected / exposed	4 / 13915 (0.03%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Cellulitis			
subjects affected / exposed	6 / 13915 (0.04%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	8 / 13915 (0.06%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 8	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	6 / 13915 (0.04%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			

subjects affected / exposed	50 / 13915 (0.36%)	35 / 6939 (0.50%)	
occurrences causally related to treatment / all	0 / 50	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chikungunya Virus Infection			
subjects affected / exposed	8 / 13915 (0.06%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chorioamnionitis			
subjects affected / exposed	3 / 13915 (0.02%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Sinusitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Tonsillitis			
subjects affected / exposed	1 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cutaneous Anthrax			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue Fever			
subjects affected / exposed	101 / 13915 (0.73%)	94 / 6939 (1.35%)	
occurrences causally related to treatment / all	0 / 104	0 / 94	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometritis			

subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometritis Decidual			
subjects affected / exposed	3 / 13915 (0.02%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis Infectious			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	2 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
External Ear Cellulitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Infection Toxoplasmal			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flavivirus Infection			
subjects affected / exposed	3 / 13915 (0.02%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	34 / 13915 (0.24%)	21 / 6939 (0.30%)	
occurrences causally related to treatment / all	0 / 34	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Bacterial			

subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Viral			
subjects affected / exposed	3 / 13915 (0.02%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Bacterial Infection			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Infection			
subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Viral Infection			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital Infection Female			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genitourinary Tract Infection			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granuloma Inguinale			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1n1 Influenza			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiv Infection			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiv Infection Cdc Category A3			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helminthic Infection			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			
subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis Viral			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes Zoster			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes Zoster Ophthalmic			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected Bites			

subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious Mononucleosis			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective Myositis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leptospirosis			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Infection			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaria			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastitis			

subjects affected / exposed	4 / 13915 (0.03%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastitis Postpartum			
subjects affected / exposed	1 / 13915 (0.01%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis Bacterial			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis Viral			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mononucleosis Syndrome			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mumps			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycoplasma Infection			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			

subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	5 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis Chronic			
subjects affected / exposed	4 / 13915 (0.03%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis Media			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis Media Chronic			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Mumps			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panencephalitis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Parasitic Gastroenteritis			

subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic Inflammatory Disease			
subjects affected / exposed	10 / 13915 (0.07%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 11	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal Abscess			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal Infection			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital Cellulitis			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar Abscess			
subjects affected / exposed	2 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngotonsillitis			
subjects affected / exposed	3 / 13915 (0.02%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal Cyst			
subjects affected / exposed	5 / 13915 (0.04%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	18 / 13915 (0.13%)	13 / 6939 (0.19%)	
occurrences causally related to treatment / all	0 / 18	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Bacterial			
subjects affected / exposed	4 / 13915 (0.03%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Mycoplasmal			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Procedural Infection			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Wound Infection			
subjects affected / exposed	6 / 13915 (0.04%)	4 / 6939 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpartum Sepsis			
subjects affected / exposed	4 / 13915 (0.03%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Tuberculosis			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	10 / 13915 (0.07%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 12	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis Acute			

subjects affected / exposed	7 / 13915 (0.05%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal Abscess			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonellosis			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scarlet Fever			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secondary Syphilis			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Infection			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Infection			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous Abscess			
subjects affected / exposed	13 / 13915 (0.09%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 13	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syphilis			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	2 / 13915 (0.01%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis Bacterial			
subjects affected / exposed	2 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth Abscess			
subjects affected / exposed	6 / 13915 (0.04%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxoplasmosis			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Typhoid Fever			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 13915 (0.02%)	3 / 6939 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	118 / 13915 (0.85%)	59 / 6939 (0.85%)	
occurrences causally related to treatment / all	0 / 127	0 / 69	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection Bacterial			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal Infection			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	3 / 13915 (0.02%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Cardiomyopathy			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Infection			
subjects affected / exposed	10 / 13915 (0.07%)	7 / 6939 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visceral Leishmaniasis			
subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval Abscess			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection			
subjects affected / exposed	5 / 13915 (0.04%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 13915 (0.00%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	0 / 13915 (0.00%)	2 / 6939 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Ketoacidosis			
subjects affected / exposed	2 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			

subjects affected / exposed	1 / 13915 (0.01%)	0 / 6939 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 Diabetes Mellitus			
subjects affected / exposed	1 / 13915 (0.01%)	1 / 6939 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	CYD Dengue Vaccine Group	Placebo Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1038 / 13915 (7.46%)	515 / 6939 (7.42%)	
Nervous system disorders			
Headache			
subjects affected / exposed[1]	753 / 1333 (56.49%)	388 / 664 (58.43%)	
occurrences (all)	1385	652	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed[2]	500 / 1333 (37.51%)	253 / 664 (38.10%)	
occurrences (all)	771	366	
Injection Site Erythema			
subjects affected / exposed[3]	83 / 1333 (6.23%)	44 / 664 (6.63%)	
occurrences (all)	99	52	
Injection Site Pain			
subjects affected / exposed[4]	650 / 1333 (48.76%)	270 / 664 (40.66%)	
occurrences (all)	1056	384	
Injection Site Swelling			
subjects affected / exposed[5]	77 / 1333 (5.78%)	27 / 664 (4.07%)	
occurrences (all)	92	32	
Malaise			
subjects affected / exposed[6]	539 / 1333 (40.44%)	264 / 664 (39.76%)	
occurrences (all)	853	383	
Pyrexia			

subjects affected / exposed[7]	238 / 1333 (17.85%)	127 / 664 (19.13%)	
occurrences (all)	270	142	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed[8]	578 / 1333 (43.36%)	267 / 664 (40.21%)	
occurrences (all)	921	400	
Infections and infestations			
Influenza			
subjects affected / exposed[9]	76 / 1333 (5.70%)	37 / 664 (5.57%)	
occurrences (all)	80	40	
Nasopharyngitis			
subjects affected / exposed[10]	150 / 1333 (11.25%)	60 / 664 (9.04%)	
occurrences (all)	163	70	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Non-serious adverse events were assessed in a subset of subjects in each group, in

accordance with the protocol.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 January 2011	Major modifications included Venezuela declined its participation, clarified efficacy during the Active Phase, end of febrile episode was further clarified, frequency of contact during the Hospital Phase was increased to 1 every 3 months, potential manifestations of severity were updated, clarified that the safety surveillance was conducted by the Principal Investigators, transaminases were available to add in the assessment of the severity of confirmed dengue cases, clarification on the reporting of SAEs during the Active Phase and the Hospital Phase, and clarification on subjects who discontinued from vaccination or trial and their continuation in the study for surveillance purposes.
03 August 2011	Clarified collection periods of acute and convalescent samples, SAE reporting period was extended throughout the entire study, clarified that laboratory staff was blinded to treatment allocation, age stratification was clarified (9 to 11 years and 12 to 16 years), updated time window of assessment of serious viscerotropic disease, and introduced the use of the WHO Verbal Autopsy Questionnaire.
29 May 2013	Modified the testing algorithm for the virological-confirmation of dengue cases to maximize the likelihood of detecting dengue cases, updated and clarified text of secondary objectives as it relates to the assessment of the CYD dengue vaccine in preventing symptomatic virologically-confirmed cases, Hospital Phase was extended by 2 years to allow a 5 year follow-up period after the last vaccination, "Other Objectives" section was added, and included re-consenting of subjects for the 2-year extension and for additional testing to identify the dengue virus.
25 January 2015	An enhanced surveillance system (the SEP) following 1 year or more of the Hospital Phase was implemented, the trial's objectives and endpoints were updated to be consistent with additional study goals, the management of suspected dengue cases was modified.
20 June 2016	Section 5.1.1 “Trial Design” was updated to add the anti Zika antibody detection, the detection of Zika infection in febrile episodes occurring from start of 2013 (retrospectively) until the end of the trial, in order to differentiate Zika cases from Dengue cases; and the Zika virus sequencing on Zika infection positive samples, three objectives were added in Section 2.3. “Other Objectives”, the definition of clinically severe dengue cases was clarified, endpoints corresponding to the 3 additional objectives were added, in Section 5.1.4, the use of the blood samples for anti-Zika antibody response evaluation was added, in Section 12.1.3. “Statistical Methods for other objectives” a new subsection (Relationship between Dengue and Zika) was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported