



## 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	<ul style="list-style-type: none"><li>• Correction of full data set</li><li>Updated safety optional field</li></ul>

### Trial information

#### Trial identification

Sponsor protocol code	CYD15
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#### 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:

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**Results analysis stage**

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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:

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**General information about the trial**

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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:

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**Population of trial subjects**

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**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:

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**Subjects enrolled per age group**

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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
<b>Arm title</b>	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.

<b>Arm title</b>	Placebo group
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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.

<b>Number of subjects in period 1</b>	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
<b>Arm title</b>	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.

<b>Arm title</b>	Placebo Group
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### 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.

<b>Number of subjects in period 2</b>	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 $\geq 38^{\circ}\text{C}$ 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

<b>Statistical analysis title</b>	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
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End point description:

Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature  $\geq 38^{\circ}\text{C}$  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
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End point timeframe:

Day 0 up to 13 months post-injection 3

<b>End point values</b>	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**

<b>Statistical analysis title</b>	Vaccine efficacy of the CYD dengue vaccine
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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
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End point description:

Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature  $\geq 38^{\circ}\text{C}$  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
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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
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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
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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 $\geq 38^{\circ}\text{C}$ 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

<b>End point values</b>	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**

<b>Statistical analysis title</b>	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
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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 ( $\geq 38^{\circ}\text{C}$ ) and continuous, lasting 2 to 7days and (b)any of the pre-listed hemorrhagic manifestations and laboratory findings of thrombocytopenia (platelet  $\leq 100 \times 10^9/\text{L}$ ) and plasma leakage as shown by hemococoncentration (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
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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
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End point description:

The 1997 WHO criteria: a)Fever: acute onset, high ( $\geq 38^{\circ}\text{C}$ ) and continuous, for 2 to 7days and (b)any of the following: thrombocytopenia (platelet $\leq 100 \times 10^9/\text{L}$ ) 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
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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
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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  $\geq 38^{\circ}\text{C}$  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  $\geq 38^{\circ}\text{C}$  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

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

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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
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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  $\leq 100000/\mu\text{l}$  and bleeding (tourniquet, petechiae or any bleeding) plus plasma leakage 2) Shock (pulse pressure  $\leq 20\text{mmHg}$  in child, or hypotension [ $\leq 90\text{mmHg}$ ] 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  $>1000\text{IU/L}$  or prothrombin time [PT] International normalized ratio [INR]  $>1.5$ ) excluding other causes of viral hepatitis 6) Impaired kidney function (serum creatinine  $\geq 1.5\text{mg/dL}$ ) 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
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End point timeframe:

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

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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		

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**Statistical analyses**

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No statistical analyses for this end point

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**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**

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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
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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  $\leq 100000/\mu\text{l}$  and bleeding (tourniquet, petechiae or any bleeding) plus plasma leakage 2) Shock (pulse pressure  $\leq 20\text{mmHg}$  in a child, or hypotension [ $\leq 90\text{mmHg}$ ] 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  $>1000\text{IU/L}$  or PT INR  $>1.5$ ) excluding other causes of viral hepatitis 6) Impaired kidney function (serum creatinine  $\geq 1.5\text{mg/dL}$ ) 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
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End point timeframe:

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

<b>End point values</b>	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 $\geq 10$ 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 $\geq 10$ 1/Dil Against Each Dengue Virus Serotype Before and Following Injection (Inj.) With CYD Dengue Vaccine or Placebo
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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
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End point timeframe:

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

<b>End point values</b>	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
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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
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End point timeframe:

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

<b>End point values</b>	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
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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,  $\geq 50$  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
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End point timeframe:

Within 7 days after each and any injection

<b>End point values</b>	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		
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## 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: $\geq 39^{\circ}\text{C}$ ; 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 reactogenicity. 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
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	14.0

### Reporting groups

Reporting group title	CYD Dengue Vaccine Group
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Reporting group description:

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

Reporting group title	Placebo Group
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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
<b>Bone Giant Cell Tumour</b>		
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
<b>Bone Sarcoma</b>		
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
<b>Brain Neoplasm Malignant</b>		
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
<b>Chondrosarcoma</b>		
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
<b>Chronic Myeloid Leukaemia</b>		
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
<b>Desmoid Tumour</b>		
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
<b>Fibroadenoma Of Breast</b>		
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
<b>Haemangioma Of Skin</b>		

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	
<b>Pituitary Tumour Benign</b>			
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	
<b>Thyroid Cancer</b>			
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	
<b>Uterine Leiomyoma</b>			
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	
<b>Vascular disorders</b>			
<b>Hypertensive Crisis</b>			
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	
<b>Secondary Hypertension</b>			
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	
<b>Surgical and medical procedures</b>			
<b>Abortion Induced</b>			
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	
<b>Abortion Induced Complete</b>			
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	
<b>Caesarean Section</b>			

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	
<b>Cholecystectomy</b>			
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	
<b>Obesity Surgery</b>			
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	
<b>Scoliosis Surgery</b>			
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	
<b>Surgery</b>			
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	
<b>Umbilical Hernia Repair</b>			
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	
<b>Pregnancy, puerperium and perinatal conditions</b>			
<b>Abnormal Product Of Conception</b>			
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	
<b>Abortion</b>			
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	
<b>Abortion Complete</b>			

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
<b>Abortion Spontaneous Incomplete</b>		
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
<b>Abortion Spontaneous Incomplete Complicated</b>		
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
<b>Abortion Threatened</b>		
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
<b>Amniorrhexis</b>		
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
<b>Antepartum Haemorrhage</b>		
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
<b>Blighted Ovum</b>		
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
<b>Cephalo-Pelvic Disproportion</b>		
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
<b>Cervical Incompetence</b>		

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
<b>Hellp Syndrome</b>		
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
<b>High Risk Pregnancy</b>		
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
<b>Hyperemesis Gravidarum</b>		
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
<b>Intra-Uterine Death</b>		
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
<b>Intrapartum Haemorrhage</b>		
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
<b>Oligohydramnios</b>		
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
<b>Placental Insufficiency</b>		
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
<b>Postpartum Haemorrhage</b>		

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	
<b>Retained Placenta Or Membranes</b>			
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	
<b>Retained Products Of Conception</b>			
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	
<b>Ruptured Ectopic Pregnancy</b>			
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	
<b>Stillbirth</b>			
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	
<b>Threatened Labour</b>			
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	
<b>General disorders and administration site conditions</b>			
<b>Catheter Site Phlebitis</b>			
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	
<b>Cyst</b>			
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	
<b>Death</b>			

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	
<b>Immune system disorders</b>			
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	
<b>Social circumstances</b>			
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
<b>Gynaecomastia</b>		
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
<b>Haematocolpos</b>		
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
<b>Haematosalpinx</b>		
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
<b>Haemorrhagic Ovarian Cyst</b>		
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
<b>Metrorrhagia</b>		
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
<b>Ovarian Cyst</b>		
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
<b>Ovarian Cyst Ruptured</b>		
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
<b>Ovarian Torsion</b>		

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
<b>Aspiration</b>		
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
<b>Asthma</b>		
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
<b>Asthmatic Crisis</b>		
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
<b>Bronchial Obstruction</b>		
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
<b>Epistaxis</b>		
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
<b>Haemothorax</b>		
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
<b>Nasal Septum Deviation</b>		
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
<b>Nasal Turbinate Hypertrophy</b>		

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
<b>Oropharyngeal Pain</b>		
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
<b>Pleurisy</b>		
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
<b>Pneumothorax</b>		
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
<b>Pulmonary Artery Stenosis</b>		
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
<b>Pulmonary Embolism</b>		
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
<b>Pulmonary Oedema</b>		
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
<b>Respiratory Tract Haemorrhage</b>		
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
<b>Status Asthmaticus</b>		

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	
<b>Hepatobiliary disorders</b>			
<b>Autoimmune Hepatitis</b>			
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	
<b>Bile Duct Stone</b>			
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	
<b>Cholecystitis</b>			
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	
<b>Cholecystitis Acute</b>			
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	
<b>Cholecystitis Chronic</b>			
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	
<b>Cholelithiasis</b>			
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	
<b>Cholestasis Of Pregnancy</b>			
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	
<b>Gallbladder Disorder</b>			

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	
<b>Hepatitis</b>			
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	
<b>Hepatitis Acute</b>			
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	
<b>Hepatitis Toxic</b>			
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	
<b>Hydrocholecystis</b>			
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	
<b>Jaundice</b>			
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	
<b>Investigations</b>			
<b>Investigation</b>			
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	
<b>Injury, poisoning and procedural complications</b>			
<b>Abdominal Injury</b>			
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
<b>Eye Injury</b>		
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
<b>Eye Penetration</b>		
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
<b>Face Injury</b>		
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
<b>Facial Bones Fracture</b>		
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
<b>Fall</b>		
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
<b>Femur Fracture</b>		
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
<b>Fibula Fracture</b>		
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
<b>Foot Fracture</b>		

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
<b>Forearm Fracture</b>		
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
<b>Foreign Body</b>		
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
<b>Foreign Body In Eye</b>		
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
<b>Genital Injury</b>		
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
<b>Gun Shot Wound</b>		
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
<b>Hand Fracture</b>		
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
<b>Head Injury</b>		
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
<b>Humerus Fracture</b>		

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
<b>Injury</b>		
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
<b>Intentional Overdose</b>		
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
<b>Joint Dislocation</b>		
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
<b>Joint Injury</b>		
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
<b>Limb Crushing Injury</b>		
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
<b>Limb Injury</b>		
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
<b>Limb Traumatic Amputation</b>		
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
<b>Lower Limb Fracture</b>		

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
<b>Lumbar Vertebral Fracture</b>		
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
<b>Meniscus Lesion</b>		
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
<b>Multiple Fractures</b>		
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
<b>Multiple Injuries</b>		
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
<b>Muscle Injury</b>		
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
<b>Nerve Injury</b>		
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
<b>Open Wound</b>		
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
<b>Perineal Laceration</b>		

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
<b>Road Traffic Accident</b>		
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
<b>Skull Fracture</b>		
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
<b>Soft Tissue Injury</b>		
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
<b>Spinal Cord Injury</b>		
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
<b>Spinal Cord Injury Cervical</b>		
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
<b>Sports Injury</b>		
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
<b>Stab Wound</b>		
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
<b>Tendon Injury</b>		

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	
<b>Ulnar Nerve Injury</b>			
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	
<b>Upper Limb Fracture</b>			
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	
<b>Vascular Access Complication</b>			
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	
<b>Wound</b>			
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	
<b>Wrist Fracture</b>			
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	
<b>Congenital, familial and genetic disorders</b>			
<b>Arteriovenous Malformation</b>			
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	
<b>Atrial Septal Defect</b>			
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	
<b>Cryptorchism</b>			

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	
<b>Hereditary Spherocytosis</b>			
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	
<b>Phimosis</b>			
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	
<b>Sickle Cell Trait</b>			
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	
<b>Cardiac disorders</b>			
<b>Tachycardia</b>			
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	
<b>Wolff-Parkinson-White Syndrome</b>			
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	
<b>Nervous system disorders</b>			
<b>Acute Disseminated Encephalomyelitis</b>			
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	
<b>Acute Polyneuropathy</b>			
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
<b>Intracranial Aneurysm</b>		
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
<b>Migraine</b>		
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
<b>Migraine With Aura</b>		
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
<b>Migraine Without Aura</b>		
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
<b>Neuropathy Peripheral</b>		
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
<b>Partial Seizures</b>		
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
<b>Post-Traumatic Headache</b>		
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
<b>Status Epilepticus</b>		

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	
<b>Status Migrainosus</b>			
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	
<b>Syncope</b>			
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	
<b>Viith Nerve Paralysis</b>			
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	
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
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	
<b>Anaemia Of Pregnancy</b>			
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	
<b>Aplastic Anaemia</b>			
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	
<b>Haemorrhagic Anaemia</b>			
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	
<b>Idiopathic Thrombocytopenic Purpura</b>			

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	
<b>Iron Deficiency Anaemia</b>			
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	
<b>Lymphadenitis</b>			
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	
<b>Lymphadenopathy</b>			
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	
<b>Lymphoid Tissue Hyperplasia</b>			
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	
<b>Thrombocytopenia</b>			
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	
<b>Thrombocytopenic Purpura</b>			
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	
<b>Ear and labyrinth disorders</b>			
<b>Tympanic Membrane Perforation</b>			
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	
<b>Vertigo</b>			

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	
<b>Eye disorders</b>			
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	
<b>Gastrointestinal disorders</b>			
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	
<b>Subcutaneous Nodule</b>			
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	
<b>Urticaria</b>			
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	
<b>Renal and urinary disorders</b>			
<b>Calculus Ureteric</b>			
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	
<b>Calculus Urethral</b>			
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	
<b>Calculus Urinary</b>			
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	
<b>Cystitis Haemorrhagic</b>			
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	
<b>Glomerulonephritis</b>			
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	
<b>Haematuria</b>			

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
<b>Lupus Nephritis</b>		
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
<b>Nephritic Syndrome</b>		
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
<b>Nephrolithiasis</b>		
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
<b>Post Streptococcal Glomerulonephritis</b>		
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
<b>Renal Colic</b>		
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
<b>Renal Failure</b>		
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
<b>Renal Tubular Necrosis</b>		
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
<b>Tubulointerstitial Nephritis</b>		

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	
<b>Urogenital Haemorrhage</b>			
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	
<b>Endocrine disorders</b>			
<b>Basedow's Disease</b>			
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	
<b>Hypothalamo-Pituitary Disorder</b>			
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	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Ankle Deformity</b>			
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	
<b>Arthropathy</b>			
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	
<b>Back Pain</b>			
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	
<b>Epiphysiolysis</b>			
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	
<b>Sacroiliitis</b>			
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	
<b>Synovial Cyst</b>			
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	
<b>Systemic Lupus Erythematosus</b>			
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	
<b>Infections and infestations</b>			
<b>Abdominal Abscess</b>			
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	
<b>Abortion Infected</b>			
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	
<b>Abscess</b>			
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	
<b>Abscess Limb</b>			
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	
<b>Abscess Neck</b>			

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
<b>Abscess Of Salivary Gland</b>		
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
<b>Abscess Oral</b>		
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
<b>Acute Sinusitis</b>		
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
<b>Acute Tonsillitis</b>		
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
<b>Adenoiditis</b>		
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
<b>Amniotic Cavity Infection</b>		
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
<b>Amoebiasis</b>		
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
<b>Amoebic Dysentery</b>		

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
<b>Anal Abscess</b>		
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
<b>Anogenital Warts</b>		
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
<b>Appendicitis</b>		
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
<b>Appendicitis Perforated</b>		
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
<b>Arthritis Bacterial</b>		
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
<b>Arthritis Infective</b>		
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
<b>Asymptomatic Hiv Infection</b>		
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
<b>Bacterial Infection</b>		

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
<b>Bartholin's Abscess</b>		
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
<b>Breast Abscess</b>		
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
<b>Breast Cellulitis</b>		
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
<b>Bronchiolitis</b>		
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
<b>Bronchitis</b>		
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
<b>Bronchopneumonia</b>		
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
<b>Carbuncle</b>		
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
<b>Cellulitis</b>		

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
<b>Gastroenteritis Viral</b>		
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
<b>Gastrointestinal Bacterial Infection</b>		
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
<b>Gastrointestinal Infection</b>		
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
<b>Gastrointestinal Viral Infection</b>		
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
<b>Genital Infection Female</b>		
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
<b>Genitourinary Tract Infection</b>		
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
<b>Granuloma Inguinale</b>		
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
<b>H1n1 Influenza</b>		

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
<b>Infectious Mononucleosis</b>		
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
<b>Infective Myositis</b>		
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
<b>Influenza</b>		
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
<b>Leptospirosis</b>		
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
<b>Lower Respiratory Tract Infection</b>		
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
<b>Lung Infection</b>		
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
<b>Malaria</b>		
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
<b>Mastitis</b>		

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
<b>Mastitis Postpartum</b>		
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
<b>Mastoiditis</b>		
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
<b>Meningitis Bacterial</b>		
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
<b>Meningitis Viral</b>		
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
<b>Mononucleosis Syndrome</b>		
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
<b>Mumps</b>		
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
<b>Mycoplasma Infection</b>		
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
<b>Nasopharyngitis</b>		

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	
<b>Orchitis</b>			
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	
<b>Osteomyelitis</b>			
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	
<b>Osteomyelitis Chronic</b>			
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	
<b>Otitis Media</b>			
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	
<b>Otitis Media Chronic</b>			
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	
<b>Pancreatitis Mumps</b>			
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	
<b>Panencephalitis</b>			
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	
<b>Parasitic Gastroenteritis</b>			

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
<b>Retroperitoneal Abscess</b>		
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
<b>Salmonellosis</b>		
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
<b>Scarlet Fever</b>		
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
<b>Secondary Syphilis</b>		
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
<b>Sepsis</b>		
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
<b>Sinusitis</b>		
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
<b>Skin Infection</b>		
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
<b>Soft Tissue Infection</b>		

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
<b>Subcutaneous Abscess</b>		
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
<b>Syphilis</b>		
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
<b>Tonsillitis</b>		
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
<b>Tonsillitis Bacterial</b>		
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
<b>Tooth Abscess</b>		
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
<b>Toxoplasmosis</b>		
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
<b>Tracheitis</b>		
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
<b>Tuberculosis</b>		

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	
<b>Viral Infection</b>			
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	
<b>Visceral Leishmaniasis</b>			
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	
<b>Vulval Abscess</b>			
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	
<b>Wound Infection</b>			
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	
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
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	
<b>Diabetes Mellitus Inadequate Control</b>			
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	
<b>Diabetic Ketoacidosis</b>			
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	
<b>Hypoglycaemia</b>			

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 %

<b>Non-serious adverse events</b>	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 <sup>[1]</sup>	753 / 1333 (56.49%)	388 / 664 (58.43%)
occurrences (all)	1385	652
General disorders and administration site conditions		
Asthenia		
subjects affected / exposed <sup>[2]</sup>	500 / 1333 (37.51%)	253 / 664 (38.10%)
occurrences (all)	771	366
Injection Site Erythema		
subjects affected / exposed <sup>[3]</sup>	83 / 1333 (6.23%)	44 / 664 (6.63%)
occurrences (all)	99	52
Injection Site Pain		
subjects affected / exposed <sup>[4]</sup>	650 / 1333 (48.76%)	270 / 664 (40.66%)
occurrences (all)	1056	384
Injection Site Swelling		
subjects affected / exposed <sup>[5]</sup>	77 / 1333 (5.78%)	27 / 664 (4.07%)
occurrences (all)	92	32
Malaise		
subjects affected / exposed <sup>[6]</sup>	539 / 1333 (40.44%)	264 / 664 (39.76%)
occurrences (all)	853	383
Pyrexia		

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