Clinical trial results:
A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of MEDI-524, a Humanized Enhanced Potency Monoclonal Antibody against Respiratory Syncytial Virus (RSV), in Children with Hemodynamically Significant Congenital Heart Disease

Summary

EudraCT number	2005-001671-35
Trial protocol	HU GB SE CZ BE DE DK AT ES Outside EU/EEA
Global end of trial date	26 June 2008

Results information

Result version number	v1 (current)
This version publication date	23 February 2017
First version publication date	23 February 2017

Trial information

Trial identification

Sponsor protocol code	MI-CP124

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00538785
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedImmune, LLC
Sponsor organisation address	Milstein Building, Granta Park, Cambridge, United Kingdom, CB21 6GH
Public contact	Pamela Griffin, Senior Director, Clinical Development, MedImmune, LLC, griffinp@medimmune.com
Scientific contact	Pamela Griffin, Senior Director, Clinical Development, MedImmune, LLC, griffinp@medimmune.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 June 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 June 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to describe the safety and tolerability of motavizumab when given monthly as prophylaxis against serious Respiratory Syncytial Virus (RSV) infection among children with hemodynamically significant congenital heart disease (CHD). This study also described the incidence of RSV hospitalization in children with hemodynamically significant CHD given motavizumab or palivizumab for prophylaxis against serious RSV disease and the incidence of RSV outpatient medically-attended lower respiratory.

Protection of trial subjects:

Adverse events (AEs), serious adverse events (SAEs), and concomitant medications were collected from the period immediately following the first administration of study drug through Study Day 150. Blood was collected prior to the first and last doses of study drug for serum chemistry (aspartate aminotransferase [AST], alanine aminotransferase [ALT], blood urea nitrogen [BUN], and creatinine) as part of the safety evaluation; vital signs were measured prior to and 30 minutes after each dose of study drug. Subjects were evaluated just prior to each dose of study drug, with a final post-dosing follow-up evaluation at Study Day 150.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 October 2005
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	5 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 14
Country: Number of subjects enrolled	Belgium: 54
Country: Number of subjects enrolled	Czech Republic: 74
Country: Number of subjects enrolled	France: 28
Country: Number of subjects enrolled	Germany: 66
Country: Number of subjects enrolled	Hungary: 53
Country: Number of subjects enrolled	Poland: 99
Country: Number of subjects enrolled	Spain: 57
Country: Number of subjects enrolled	Sweden: 21
Country: Number of subjects enrolled	United Kingdom: 57
Country: Number of subjects enrolled	Canada: 49
Country: Number of subjects enrolled	United States: 301

Country: Number of subjects enrolled	Bulgaria: 36
Country: Number of subjects enrolled	Israel: 132
Country: Number of subjects enrolled	Lebanon: 128
Country: Number of subjects enrolled	Russian Federation: 66
Worldwide total number of subjects	1235
EEA total number of subjects	545

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	1235
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 1236 subjects were randomized, out of which one subject was not analyzed as was randomized without proper citizenship, at 162 sites in 16 countries within the northern hemisphere between 21Oct2005 and 14Dec2005 in Season 1 and 02Oct2007 and 31Dec2007 in Season 2; each subject participated in the study for a single RSV season.

Pre-assignment

Screening details:

Subjects were randomized 1:1 on Study Day 0 to receive either 15 mg/kg motavizumab or 15 mg/kg palivizumab. A permuted-block randomization method was used and a separate randomization schedule was generated for each site and cyanotic CHD strata combination.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Motavizumab (MEDI-524)

Arm description:

Motavizumab was administered as an intramuscular injection at 15 mg/kg every 30 days during the RSV season for a total of 5 scheduled injections. Additionally, children who underwent cardiac surgery with cardiopulmonary bypass through Study Day 150 were to receive a protocol-specified replacement dose of study drug immediately following the surgery when determined by the physician to be medically stable for an IM injection.

Arm type	Experimental
Investigational medicinal product name	Motavizumab
Investigational medicinal product code	MEDI-524
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

100 mg/mL

Arm title	Palivizumab

Arm description:

Palivizumab was administered as an intramuscular injection at 15 mg/kg every 30 days during the RSV season for a total of 5 scheduled injections. Additionally, children who underwent cardiac surgery with cardiopulmonary bypass through Study Day 150 were to receive a protocol-specified replacement dose of study drug immediately following the surgery when determined by the physician to be medically stable for an IM injection.

Arm type	Experimental
Investigational medicinal product name	Palivizumab
Investigational medicinal product code	MEDI-493
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

100 mg/mL

Number of subjects in period 1	Motavizumab (MEDI-524)	Palivizumab
Started	623	612
Completed	604	595
Not completed	19	17
Adverse event, serious fatal	9	10
Withdrawal of consent	9	7
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	1235	1235	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	1235	1235	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous | Units: months			
arithmetic mean	8.33		
standard deviation	± 6.45	-	
Gender, Male/Female Units: participants			
Female	580	580	
Male	655	655	
Race/Ethnicity, Customized Units: Subjects			
White/Non-hispanic	1069	1069	
Black	43	43	
Hispanic	44	44	
Asian	18	18	
Other	61	61	
Region of Enrollment Units: Subjects			
United States	301	301	
Spain	57	57	
Lebanon	128	128	
Austria	14	14	
Israel	132	132	
Russian Federation	66	66	
United Kingdom	57	57	
France	28	28	
Czech Republic	74	74	
Hungary	53	53	
Canada	49	49	

Belgium	54	54	
Poland	99	99	
Bulgaria	36	36	
Germany	66	66	
Sweden	21	21	

End points

End points reporting groups

Reporting group title	Motavizumab (MEDI-524)

Reporting group description:

Motavizumab was administered as an intramuscular injection at 15 mg/kg every 30 days during the RSV season for a total of 5 scheduled injections. Additionally, children who underwent cardiac surgery with cardiopulmonary bypass through Study Day 150 were to receive a protocol-specified replacement dose of study drug immediately following the surgery when determined by the physician to be medically stable for an IM injection.

Reporting group title	Palivizumab

Reporting group description:

Palivizumab was administered as an intramuscular injection at 15 mg/kg every 30 days during the RSV season for a total of 5 scheduled injections. Additionally, children who underwent cardiac surgery with cardiopulmonary bypass through Study Day 150 were to receive a protocol-specified replacement dose of study drug immediately following the surgery when determined by the physician to be medically stable for an IM injection.

Primary: Number of Subjects Reporting Adverse Events Through Study Day 150

End point title	Number of Subjects Reporting Adverse Events Through Study Day 150[1]

End point description:

Adverse events were summarized by system organ class (SOC) and preferred term (using MedDRA Version 11.1) overall.

End point type	Primary

End point timeframe:

Days 0-150

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)	Palivizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	618	612		
Units: participants	575	566		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Serious Adverse Events Through Study Day 150

End point title	Number of Subjects Reporting Serious Adverse Events Through Study Day 150[2]

End point description:

Serious adverse events were those that resulted in death; were life-threatening; resulted in subject hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability or incapacity; or were an important medical event that may not have resulted in death, threatened life, or required hospitalization and that, based on appropriate medical judgment, may have jeopardized the

subject and may have required medical or surgical intervention to prevent one of the outcomes listed above.

End point type	Primary

End point timeframe:

Days 0-150

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)	Palivizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	618	612		
Units: participants	292	304		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Laboratory Adverse Events

End point title	Number of Subjects Reporting Laboratory Adverse Events[3]

End point description:

End point type	Primary

End point timeframe:

Days 0-150

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)	Palivizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	618	612		
Units: participants				
Adrenal insufficiency	3	3		
Alanine aminotranferase increased	13	26		
Anemia	17	14		
Aspartate aminotransferase increased	3	9		
Bacteria sputum indentified	1	1		
Blood alkaline phosphatase increased	1	0		
Blood calcium decreased	0	1		
Blood calcium increased	2	0		
Blood creatinine increased	0	1		
Blood potassium decreased	1	1		
Blood potassium increased	1	1		
Blood sodium abnormal	0	1		
Blood sodium decreased	1	1		

Blood thyroid stimulating hormone increased	1	0		
Blood urea increased	39	34		
Brain natriuretic peptide increased	1	0		
C-reactive protein increased	0	5		
Clostridium difficiline toxin test positive	1	0		
Coagulation test abnormal	1	1		
Haematocrit drecreased	0	1		
Haemaglobin decreased	0	1		
Hepatic enzyme increased	3	3		
Hyperbilirubinemia	1	0		
Hypertransaminasemia	0	1		
Hypothyroidism	3	2		
International normalised ratio decreased	0	1		
International normalised ratio increased	0	2		
Iron deficiency anaemia	1	0		
Liver function test abnormal	3	2		
Mean cell volume decreased	1	0		
Neutropenia	1	0		
Occult blood positive	1	0		
Oxygen saturation decreased	9	4		
Platelet count decreased	0	1		
Renal function test abnormal	1	0		
Thrombocythemia	1	0		
Thrombocytopenia	1	5		
Thyroid function test abnormal	0	1		
Transaminases increased	0	2		
Urine output decreased	1	1		
White blood cell count increased	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of Respiratory Syncytial Virus (RSV) hospitaliztion

End point title	Incidence of Respiratory Syncytial Virus (RSV) hospitaliztion

End point description:

An RSV hospitalization was defined as one of the following: 1) Cardiac/respiratory hospitalization with a positive real-time RT-PCR RSV diagnostic test performed at a central laboratory, or 2) New onset of lower respiratory tract symptoms with an objective measure of worsening respiratory status in an already hospitalized subject with a positive real-time RT-PCR RSV diagnostic test performed at a central laboratory (nosocomial RSV hospitalization), or 3) Death demonstrated to be caused by RSV (based on virologic evidence and either clinical history or autopsy).

End point type	Secondary

End point timeframe:

Days 0-150

End point values	Motavizumab (MEDI-524)	Palivizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	623	612		
Units: participants	12	16		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Relative risk and confidence interval adjusted for the stratification factor of CHD stratum (cyanotic or other) specified on the CRF

Comparison groups	Motavizumab (MEDI-524) v Palivizumab
Number of subjects included in analysis	1235
Analysis specification	Pre-specified
Analysis type	other[4]
Method	Guess method
Parameter estimate	Risk ratio (RR)
Point estimate	0.746
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.344
upper limit	1.586

Notes:

[4] - Analysis type - Descriptive: Study was not powered to show statistical superiority or non-inferiority in the efficacy endpoints.

Secondary: Incidence of respiratory syncytial virus (RSV) Medically-attended Lower Respiratory Illness (MA-LRI) for Season 2 only

End point title	Incidence of respiratory syncytial virus (RSV) Medically-attended Lower Respiratory Illness (MA-LRI) for Season 2 only

End point description:

An RSV outpatient MA-LRI was defined as an outpatient medically-attended event designated by the principal investigator as a lower respiratory illness with a positive real-time RT-PCR RSV diagnostic test performed at a central laboratory.

End point type	Secondary

End point timeframe:

Days 0-150

End point values	Motavizumab (MEDI-524)	Palivizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	304	310		
Units: participant	3	6		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Relative risk and confidence interval adjusted for the stratification factor of CHD stratum (cyanotic or other) specified on the CRF

Comparison groups	Motavizumab (MEDI-524) v Palivizumab
Number of subjects included in analysis	614
Analysis specification	Pre-specified
Analysis type	other[5]
Method	Guess method
Parameter estimate	Risk ratio (RR)
Point estimate	0.495
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.101
upper limit	1.989

Notes:

[5] - Analysis type - Descriptive: Study was not powered to show statistical superiority or non-inferiority in the efficacy endpoints.

Secondary: Number of Subjects Who Had Anti-motavizumab Antibodies Detected

End point title	Number of Subjects Who Had Anti-motavizumab Antibodies Detected[6]

End point description:

ECLA-based method

End point type	Secondary

End point timeframe:

Days 0-150

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)			
Subject group type	Reporting group			
Number of subjects analysed	605			
Units: participants	9			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Trough Serum Concentration of Motavizumab at Pre-dose 1

End point title	Mean Trough Serum Concentration of Motavizumab at Pre-dose 1[7]

End point description:

Trough serum concentrations (ug/mL) of motavizumab at pre-dose 1

End point type	Secondary

End point timeframe:

Pre-dose 1

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)			
Subject group type	Reporting group			
Number of subjects analysed	543			
Units: ug/mL				
arithmetic mean (standard deviation)	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Trough Serum Concentration of Motavizumab at 30 Days Post-dose 1

End point title	Mean Trough Serum Concentration of Motavizumab at 30 Days Post-dose 1[8]

End point description:

Trough serum concentrations (ug/mL) of motavizumab at 30 days post-dose 1

End point type	Secondary

End point timeframe:

30 days post-dose 1

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)			
Subject group type	Reporting group			
Number of subjects analysed	521			
Units: ug/mL				
arithmetic mean (standard deviation)	46.9 (± 15.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Trough Serum Concentration of Motavizumab at 30 Days Post-dose 2

End point title	Mean Trough Serum Concentration of Motavizumab at 30 Days Post-dose 2[9]

End point description:

Trough serum concentrations (ug/mL) of motavizumab at 30 days post-dose 2

End point type	Secondary

End point timeframe:

30 days post-dose 2

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)			
Subject group type	Reporting group			
Number of subjects analysed	228			
Units: ug/mL				
arithmetic mean (standard deviation)	60.94 (± 25.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Trough Serum Concentration of Motavizumab at 30 Days Post-dose 3

End point title	Mean Trough Serum Concentration of Motavizumab at 30 Days Post-dose 3[10]

End point description:

Trough serum concentrations (mcg/mL) of motavizumab at 30 days post-dose 3

End point type	Secondary

End point timeframe:

30 days post-dose 3

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)			
Subject group type	Reporting group			
Number of subjects analysed	203			
Units: ug/mL				
arithmetic mean (standard deviation)	66.59 (± 34.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Trough Serum Concentration of Motavizumab at 30 Days Post-dose 4

End point title	Mean Trough Serum Concentration of Motavizumab at 30 Days

	Post-dose 4[11]

End point description:

Trough serum concentrations (ug/mL) of motavizumab at 30 days post-dose 4

End point type	Secondary

End point timeframe:

30 days post-dose 4

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)			
Subject group type	Reporting group			
Number of subjects analysed	203			
Units: ug/mL				
arithmetic mean (standard deviation)	77.87 (± 32.75)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Trough Serum Concentrations of Motavizumab in Subjects Who Underwent Cardiac Surgery with Cardiopulmonary Bypass

End point title	Mean Trough Serum Concentrations of Motavizumab in Subjects Who Underwent Cardiac Surgery with Cardiopulmonary Bypass[12]

End point description:

Subjects who underwent cardiac surgery with cardiopulmonary bypass through Study Day 150 were to have a blood sample taken for determination of study drug concentrations prior to receipt of another dose of study drug immediately following surgery.

End point type	Secondary

End point timeframe:

Days 0-150

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical data was not planned to be reported for this endpoint

End point values	Motavizumab (MEDI-524)			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: ug/mL				
arithmetic mean (standard deviation)	48.51 (± 27.3)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 0 - Day 150	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	11.1

Reporting groups	
Reporting group title	Motavizumab (MEDI-524)
Reporting group description:	
Motavizumab was administered as an intramuscular injection at 15 mg/kg every 30 days during the RSV season for a total of 5 scheduled injections. Additionally, children who underwent cardiac surgery with cardiopulmonary bypass through Study Day 150 were to receive a protocol-specified replacement dose of study drug immediately following the surgery when determined by the physician to be medically stable for an IM injection.	
Reporting group title	Palivizumab
Reporting group description:	
Palivizumab was administered as an intramuscular injection at 15 mg/kg every 30 days during the RSV season for a total of 5 scheduled injections. Additionally, children who underwent cardiac surgery with cardiopulmonary bypass through Study Day 150 were to receive a protocol-specified replacement dose of study drug immediately following the surgery when determined by the physician to be medically stable for an IM injection.	

Serious adverse events	Motavizumab (MEDI-524)	Palivizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	292 / 618 (47.25%)	304 / 612 (49.67%)	
number of deaths (all causes)	9	10	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
AORTIC STENOSIS			
subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIAL THROMBOSIS LIMB			
subjects affected / exposed	3 / 618 (0.49%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMORAL ARTERY OCCLUSION			

subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOVOLAEMIC SHOCK			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOSIS			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASOSPASM			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
IMMUNISATION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETHRAL MEATOTOMY			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
CATHETER RELATED COMPLICATION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

CYST			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEATH			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
DRUG WITHDRAWAL SYNDROME			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IRRITABILITY			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTI-ORGAN FAILURE			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
PYREXIA			
subjects affected / exposed	5 / 618 (0.81%)	5 / 612 (0.82%)	
occurrences causally related to treatment / all	1 / 6	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Social circumstances			
SOCIAL STAY HOSPITALISATION			
subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
EPIDIDYMITIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (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	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOIDAL HYPERTROPHY			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
APNOEA			
subjects affected / exposed	1 / 618 (0.16%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
APNOEIC ATTACK			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASPIRATION			
subjects affected / exposed	1 / 618 (0.16%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
ATELECTASIS			

subjects affected / exposed	1 / 618 (0.16%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHIAL HYPERREACTIVITY			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHOPULMONARY DYSPLASIA			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHOSPASM			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOKING			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHYLOTHORAX			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
COUGH			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIAPHRAGM MUSCLE WEAKNESS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIAPHRAGMATIC HERNIA			

subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIAPHRAGMATIC PARALYSIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA			
subjects affected / exposed	2 / 618 (0.32%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOXIA			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARYNGEAL GRANULOMA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG CONSOLIDATION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFILTRATION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
subjects affected / exposed	1 / 618 (0.16%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA ASPIRATION			

subjects affected / exposed	2 / 618 (0.32%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONITIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOTHORAX			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY ARTERY STENOSIS			
subjects affected / exposed	0 / 618 (0.00%)	5 / 612 (0.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY CONGESTION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY HYPERTENSION			
subjects affected / exposed	3 / 618 (0.49%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY HYPERTENSIVE CRISIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY OEDEMA			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY VEIN OCCLUSION			

subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY VEIN STENOSIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY ARREST			
subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
RESPIRATORY DISTRESS			
subjects affected / exposed	4 / 618 (0.65%)	4 / 612 (0.65%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY FAILURE			
subjects affected / exposed	2 / 618 (0.32%)	4 / 612 (0.65%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
STRIDOR			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TACHYPNOEA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRACHEOMALACIA			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
WHEEZING			

subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CENTRAL VENOUS PRESSURE INCREASED			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COAGULATION TEST ABNORMAL			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDICAL OBSERVATION			
subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SLEEP STUDY			

subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
ACCIDENTAL OVERDOSE			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
AORTIC INJURY			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONTUSION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMUR FRACTURE			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEAD INJURY			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDICAL DEVICE COMPLICATION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE FRACTURES			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL HAEMORRHAGE			

subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTPERICARDIOTOMY SYNDROME			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEROMA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SHUNT MALFUNCTION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SHUNT OCCLUSION			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SHUNT STENOSIS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBDURAL HAEMATOMA			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER LIMB FRACTURE			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR PSEUDOANEURYSM			

subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
ANOMALOUS PULMONARY VENOUS CONNECTION			
subjects affected / exposed	2 / 618 (0.32%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
AORTIC VALVE ATRESIA			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL SEPTAL DEFECT			
subjects affected / exposed	5 / 618 (0.81%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR SEPTAL DEFECT			
subjects affected / exposed	13 / 618 (2.10%)	22 / 612 (3.59%)	
occurrences causally related to treatment / all	0 / 14	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHARGE SYNDROME			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
CLEFT LIP AND PALATE			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLEFT PALATE			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COARCTATION OF THE AORTA			

subjects affected / exposed	3 / 618 (0.49%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONGENITAL AORTIC DILATATION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONGENITAL MITRAL VALVE STENOSIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONGENITAL CORONARY ARTERY MALFORMATION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONGENITAL PULMONARY VALVE ATRESIA			
subjects affected / exposed	8 / 618 (1.29%)	14 / 612 (2.29%)	
occurrences causally related to treatment / all	0 / 10	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
CONGENITAL TRICUSPID VALVE ATRESIA			
subjects affected / exposed	8 / 618 (1.29%)	12 / 612 (1.96%)	
occurrences causally related to treatment / all	0 / 11	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVELOPMENTAL GLAUCOMA			
subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DOUBLE OUTLET RIGHT VENTRICLE			
subjects affected / exposed	10 / 618 (1.62%)	7 / 612 (1.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	

EBSTEIN'S ANOMALY			
subjects affected / exposed	0 / 618 (0.00%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
FALLOT'S TETRALOGY			
subjects affected / exposed	38 / 618 (6.15%)	49 / 612 (8.01%)	
occurrences causally related to treatment / all	0 / 45	0 / 63	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEART DISEASE CONGENITAL			
subjects affected / exposed	4 / 618 (0.65%)	9 / 612 (1.47%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDROCELE			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOPLASTIC LEFT HEART SYNDROME			
subjects affected / exposed	16 / 618 (2.59%)	18 / 612 (2.94%)	
occurrences causally related to treatment / all	0 / 23	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOPLASTIC RIGHT HEART SYNDROME			
subjects affected / exposed	2 / 618 (0.32%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOSPADIAS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERRUPTION OF AORTIC ARCH			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEFT VENTRICLE OUTFLOW TRACT			

OBSTRUCTION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDIUM-CHAIN ACETYL-COENZYME A DEHYDROGENASE DEFICIENCY			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MITRAL VALVE ATRESIA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE CARDIAC DEFECTS			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PATENT DUCTUS ARTERIOSUS			
subjects affected / exposed	4 / 618 (0.65%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PHIMOSIS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY ARTERY ATRESIA			
subjects affected / exposed	4 / 618 (0.65%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY SEQUESTRATION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYLORIC STENOSIS			

subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RIGHT VENTRICLE OUTFLOW TRACT OBSTRUCTION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SCIMITAR SYNDROME			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SHONE COMPLEX			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSPOSITION OF THE GREAT VESSELS			
subjects affected / exposed	4 / 618 (0.65%)	6 / 612 (0.98%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRUNCUS ARTERIOSUS PERSISTENT			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UNIVENTRICULAR HEART			
subjects affected / exposed	9 / 618 (1.46%)	11 / 612 (1.80%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR SEPTAL DEFECT			
subjects affected / exposed	29 / 618 (4.69%)	36 / 612 (5.88%)	
occurrences causally related to treatment / all	0 / 32	0 / 38	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEAFNESS BILATERAL			

subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
AORTIC VALVE STENOSIS			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR BLOCK COMPLETE			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ANEURYSM			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ARREST			
subjects affected / exposed	0 / 618 (0.00%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
CARDIAC FAILURE			
subjects affected / exposed	5 / 618 (0.81%)	7 / 612 (1.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
CARDIAC FAILURE ACUTE			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
CARDIAC FAILURE CHRONIC			

subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	4 / 618 (0.65%)	5 / 612 (0.82%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC PSEUDOANEURYSM			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC TAMPONADE			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	1 / 618 (0.16%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
CORONARY ARTERY OCCLUSION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYANOSIS			
subjects affected / exposed	9 / 618 (1.46%)	5 / 612 (0.82%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
DRESSLER'S SYNDROME			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEFT VENTRICULAR DYSFUNCTION			

subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MITRAL VALVE STENOSIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERICARDIAL EFFUSION			
subjects affected / exposed	2 / 618 (0.32%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY VALVE STENOSIS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TACHYCARDIA			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR DYSFUNCTION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
ANOXIC ENCEPHALOPATHY			

subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONVULSION			
subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEBRILE CONVULSION			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCLONUS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PHRENIC NERVE PARALYSIS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TONIC CLONIC MOVEMENTS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
STRABISMUS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONSTIPATION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (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	2 / 618 (0.32%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTERITIS			
subjects affected / exposed	1 / 618 (0.16%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOLITIS			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

ENTEROCUTANEOUS FISTULA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRITIS			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL INFLAMMATION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	4 / 618 (0.65%)	6 / 612 (0.98%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
INGUINAL HERNIA			
subjects affected / exposed	1 / 618 (0.16%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
INGUINAL HERNIA, OBSTRUCTIVE			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL ISCHAEMIA			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERITONEAL HAEMORRHAGE			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL HAEMORRHAGE			

subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPIGELIAN HERNIA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOLVULUS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
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 / 618 (0.16%)	4 / 612 (0.65%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URTICARIA			
subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

NEPHROLITHIASIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYELOCALIECTASIS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE ACUTE			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL TUBULAR NECROSIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTHYROIDISM			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
SOFT TISSUE NECROSIS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
ABDOMINAL SEPSIS			

subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOVIRAL UPPER RESPIRATORY INFECTION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOVIRUS INFECTION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERAEMIA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL PYELONEPHRITIS			
subjects affected / exposed	1 / 618 (0.16%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHIOLITIS			
subjects affected / exposed	15 / 618 (2.43%)	16 / 612 (2.61%)	
occurrences causally related to treatment / all	0 / 27	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
BRONCHITIS			
subjects affected / exposed	12 / 618 (1.94%)	10 / 612 (1.63%)	
occurrences causally related to treatment / all	0 / 16	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
BRONCHITIS VIRAL			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
BRONCHOPNEUMONIA			

subjects affected / exposed	4 / 618 (0.65%)	6 / 612 (0.98%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
CELLULITIS			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CROUP INFECTIOUS			
subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EAR INFECTION			
subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOCARDITIS			
subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOCARDITIS BACTERIAL			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROBACTER BACTERAEMIA			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA URINARY TRACT INFECTION			

subjects affected / exposed	1 / 618 (0.16%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS			
subjects affected / exposed	17 / 618 (2.75%)	18 / 612 (2.94%)	
occurrences causally related to treatment / all	0 / 17	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS ROTAVIRUS			
subjects affected / exposed	7 / 618 (1.13%)	14 / 612 (2.29%)	
occurrences causally related to treatment / all	0 / 7	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS VIRAL			
subjects affected / exposed	5 / 618 (0.81%)	6 / 612 (0.98%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
KLEBSIELLA SEPSIS			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
LARYNGITIS			
subjects affected / exposed	1 / 618 (0.16%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOBAR PNEUMONIA			
subjects affected / exposed	3 / 618 (0.49%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	4 / 618 (0.65%)	4 / 612 (0.65%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFECTION			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFECTION PSEUDOMONAL			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHANGITIS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDIASTINITIS			
subjects affected / exposed	1 / 618 (0.16%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENINGITIS MENINGOCOCCAL			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METAPNEUMOVIRUS INFECTION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NASOPHARYNGITIS			

subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OTITIS MEDIA			
subjects affected / exposed	5 / 618 (0.81%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OTITIS MEDIA ACUTE			
subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OTITIS MEDIA VIRAL			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARAINFLUENZAE VIRUS INFECTION			
subjects affected / exposed	0 / 618 (0.00%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
PHARYNGITIS			
subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	20 / 618 (3.24%)	23 / 612 (3.76%)	
occurrences causally related to treatment / all	0 / 27	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA ADENOVIRAL			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA INFLUENZAL			

subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSEUDOMONAL SEPSIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYELONEPHRITIS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY SYNCYTIAL VIRUS BRONCHIOLITIS			
subjects affected / exposed	6 / 618 (0.97%)	9 / 612 (1.47%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	2 / 618 (0.32%)	4 / 612 (0.65%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 618 (0.32%)	4 / 612 (0.65%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	2 / 618 (0.32%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RHINITIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ROTAVIRUS INFECTION			

subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
SINUSITIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL MEDIASTINITIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TONSILLITIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRACHEITIS			

subjects affected / exposed	2 / 618 (0.32%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	11 / 618 (1.78%)	11 / 612 (1.80%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	6 / 618 (0.97%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION PSEUDOMONAL			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VARICELLA			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL INFECTION			
subjects affected / exposed	1 / 618 (0.16%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL SINUSITIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL UPPER RESPIRATORY TRACT			

INFECTION			
subjects affected / exposed	3 / 618 (0.49%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION STAPHYLOCOCCAL			
subjects affected / exposed	0 / 618 (0.00%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	3 / 618 (0.49%)	1 / 612 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIET REFUSAL			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FAILURE TO THRIVE			
subjects affected / exposed	3 / 618 (0.49%)	5 / 612 (0.82%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEEDING DISORDER			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEEDING DISORDER OF INFANCY OR EARLY CHILDHOOD			
subjects affected / exposed	1 / 618 (0.16%)	3 / 612 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

FOOD INTOLERANCE			
subjects affected / exposed	0 / 618 (0.00%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOPHAGIA			
subjects affected / exposed	1 / 618 (0.16%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
METABOLIC ACIDOSIS			
subjects affected / exposed	1 / 618 (0.16%)	0 / 612 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WEIGHT GAIN POOR			
subjects affected / exposed	3 / 618 (0.49%)	2 / 612 (0.33%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Motavizumab (MEDI-524)	Palivizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	553 / 618 (89.48%)	540 / 612 (88.24%)	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	13 / 618 (2.10%)	25 / 612 (4.08%)	
occurrences (all)	13	25	
BLOOD UREA INCREASED			
subjects affected / exposed	39 / 618 (6.31%)	34 / 612 (5.56%)	
occurrences (all)	39	35	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	3 / 618 (0.49%)	9 / 612 (1.47%)	
occurrences (all)	3	9	
OXYGEN SATURATION DECREASED			

subjects affected / exposed	9 / 618 (1.46%)	4 / 612 (0.65%)	
occurrences (all)	10	5	
WEIGHT DECREASED			
subjects affected / exposed	7 / 618 (1.13%)	6 / 612 (0.98%)	
occurrences (all)	7	6	
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	9 / 618 (1.46%)	10 / 612 (1.63%)	
occurrences (all)	10	10	
CYANOSIS			
subjects affected / exposed	25 / 618 (4.05%)	25 / 612 (4.08%)	
occurrences (all)	42	32	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	14 / 618 (2.27%)	16 / 612 (2.61%)	
occurrences (all)	15	22	
General disorders and administration site conditions			
IRRITABILITY			
subjects affected / exposed	22 / 618 (3.56%)	37 / 612 (6.05%)	
occurrences (all)	33	48	
PYREXIA			
subjects affected / exposed	180 / 618 (29.13%)	177 / 612 (28.92%)	
occurrences (all)	285	286	
Immune system disorders			
IMMUNISATION REACTION			
subjects affected / exposed	6 / 618 (0.97%)	8 / 612 (1.31%)	
occurrences (all)	8	11	
Eye disorders			
CONJUNCTIVITIS			
subjects affected / exposed	39 / 618 (6.31%)	27 / 612 (4.41%)	
occurrences (all)	42	32	
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	69 / 618 (11.17%)	64 / 612 (10.46%)	
occurrences (all)	80	70	
CONSTIPATION			

subjects affected / exposed	44 / 618 (7.12%)	31 / 612 (5.07%)	
occurrences (all)	47	35	
FLATULENCE			
subjects affected / exposed	5 / 618 (0.81%)	6 / 612 (0.98%)	
occurrences (all)	5	7	
ENTERITIS			
subjects affected / exposed	7 / 618 (1.13%)	4 / 612 (0.65%)	
occurrences (all)	8	4	
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	19 / 618 (3.07%)	23 / 612 (3.76%)	
occurrences (all)	19	23	
TEETHING			
subjects affected / exposed	44 / 618 (7.12%)	36 / 612 (5.88%)	
occurrences (all)	54	56	
VOMITING			
subjects affected / exposed	59 / 618 (9.55%)	49 / 612 (8.01%)	
occurrences (all)	70	60	
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	3 / 618 (0.49%)	7 / 612 (1.14%)	
occurrences (all)	3	7	
NASAL CONGESTION			
subjects affected / exposed	26 / 618 (4.21%)	33 / 612 (5.39%)	
occurrences (all)	31	45	
COUGH			
subjects affected / exposed	92 / 618 (14.89%)	71 / 612 (11.60%)	
occurrences (all)	120	95	
PLEURAL EFFUSION			
subjects affected / exposed	9 / 618 (1.46%)	6 / 612 (0.98%)	
occurrences (all)	9	7	
PNEUMOTHORAX			
subjects affected / exposed	2 / 618 (0.32%)	7 / 612 (1.14%)	
occurrences (all)	2	7	
RESPIRATORY DISORDER			

subjects affected / exposed	23 / 618 (3.72%)	28 / 612 (4.58%)	
occurrences (all)	27	35	
RHINORRHOEA			
subjects affected / exposed	49 / 618 (7.93%)	45 / 612 (7.35%)	
occurrences (all)	64	70	
WHEEZING			
subjects affected / exposed	10 / 618 (1.62%)	10 / 612 (1.63%)	
occurrences (all)	10	12	
Skin and subcutaneous tissue disorders			
DERMATITIS			
subjects affected / exposed	7 / 618 (1.13%)	3 / 612 (0.49%)	
occurrences (all)	7	3	
DERMATITIS ATOPIC			
subjects affected / exposed	6 / 618 (0.97%)	3 / 612 (0.49%)	
occurrences (all)	7	3	
DERMATITIS DIAPER			
subjects affected / exposed	32 / 618 (5.18%)	31 / 612 (5.07%)	
occurrences (all)	38	38	
DERMATITIS CONTACT			
subjects affected / exposed	5 / 618 (0.81%)	7 / 612 (1.14%)	
occurrences (all)	5	7	
DRY SKIN			
subjects affected / exposed	6 / 618 (0.97%)	2 / 612 (0.33%)	
occurrences (all)	6	2	
ECZEMA			
subjects affected / exposed	11 / 618 (1.78%)	9 / 612 (1.47%)	
occurrences (all)	13	9	
RASH			
subjects affected / exposed	27 / 618 (4.37%)	21 / 612 (3.43%)	
occurrences (all)	27	25	
RASH MACULO-PAPULAR			
subjects affected / exposed	9 / 618 (1.46%)	6 / 612 (0.98%)	
occurrences (all)	10	6	
Psychiatric disorders			
RESTLESSNESS			

subjects affected / exposed	6 / 618 (0.97%)	3 / 612 (0.49%)	
occurrences (all)	7	3	
Infections and infestations			
BRONCHIOLITIS			
subjects affected / exposed	16 / 618 (2.59%)	10 / 612 (1.63%)	
occurrences (all)	18	11	
BRONCHITIS			
subjects affected / exposed	40 / 618 (6.47%)	41 / 612 (6.70%)	
occurrences (all)	48	57	
CANDIDIASIS			
subjects affected / exposed	6 / 618 (0.97%)	5 / 612 (0.82%)	
occurrences (all)	6	7	
CROUP INFECTIOUS			
subjects affected / exposed	2 / 618 (0.32%)	9 / 612 (1.47%)	
occurrences (all)	2	9	
EAR INFECTION			
subjects affected / exposed	9 / 618 (1.46%)	7 / 612 (1.14%)	
occurrences (all)	11	9	
EXANTHEMA SUBITUM			
subjects affected / exposed	6 / 618 (0.97%)	7 / 612 (1.14%)	
occurrences (all)	6	7	
GASTROENTERITIS			
subjects affected / exposed	56 / 618 (9.06%)	48 / 612 (7.84%)	
occurrences (all)	62	53	
GASTROENTERITIS VIRAL			
subjects affected / exposed	9 / 618 (1.46%)	5 / 612 (0.82%)	
occurrences (all)	9	5	
INFLUENZA			
subjects affected / exposed	6 / 618 (0.97%)	3 / 612 (0.49%)	
occurrences (all)	6	3	
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	9 / 618 (1.46%)	9 / 612 (1.47%)	
occurrences (all)	12	13	
NASOPHARYNGITIS			

subjects affected / exposed	67 / 618 (10.84%)	57 / 612 (9.31%)	
occurrences (all)	83	79	
ORAL CANDIDIASIS			
subjects affected / exposed	10 / 618 (1.62%)	7 / 612 (1.14%)	
occurrences (all)	10	11	
OTITIS MEDIA			
subjects affected / exposed	73 / 618 (11.81%)	70 / 612 (11.44%)	
occurrences (all)	97	95	
OTITIS MEDIA ACUTE			
subjects affected / exposed	26 / 618 (4.21%)	19 / 612 (3.10%)	
occurrences (all)	30	25	
PHARYNGITIS			
subjects affected / exposed	31 / 618 (5.02%)	24 / 612 (3.92%)	
occurrences (all)	37	28	
PNEUMONIA			
subjects affected / exposed	11 / 618 (1.78%)	13 / 612 (2.12%)	
occurrences (all)	12	14	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	11 / 618 (1.78%)	4 / 612 (0.65%)	
occurrences (all)	12	5	
RHINITIS			
subjects affected / exposed	91 / 618 (14.72%)	77 / 612 (12.58%)	
occurrences (all)	115	99	
SINUSITIS			
subjects affected / exposed	10 / 618 (1.62%)	7 / 612 (1.14%)	
occurrences (all)	11	8	
TONSILLITIS			
subjects affected / exposed	18 / 618 (2.91%)	8 / 612 (1.31%)	
occurrences (all)	21	8	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	160 / 618 (25.89%)	164 / 612 (26.80%)	
occurrences (all)	235	254	
URINARY TRACT INFECTION			
subjects affected / exposed	12 / 618 (1.94%)	9 / 612 (1.47%)	
occurrences (all)	13	9	

VARICELLA			
subjects affected / exposed	11 / 618 (1.78%)	5 / 612 (0.82%)	
occurrences (all)	11	5	
VIRAL INFECTION			
subjects affected / exposed	38 / 618 (6.15%)	30 / 612 (4.90%)	
occurrences (all)	47	33	
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	12 / 618 (1.94%)	15 / 612 (2.45%)	
occurrences (all)	13	16	
Metabolism and nutrition disorders			
HYPOKALAEMIA			
subjects affected / exposed	6 / 618 (0.97%)	5 / 612 (0.82%)	
occurrences (all)	6	6	
DECREASED APPETITE			
subjects affected / exposed	4 / 618 (0.65%)	6 / 612 (0.98%)	
occurrences (all)	5	6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 May 2005	MI-CP124 (Season 1) amendment-1 included that children with respiratory symptoms must have a negative RSV test prior to randomizationin order to exclude children infected with RSV from the study.
17 April 2006	MI-CP124 (Season 1) amendment-2 included the following changes: section 'Clinical Experience with MEDI-524' was updated to include the results of a review of safety date from MI-CP124 and the Phase 3 study, MI-CP110; sample size was increased from 600 subjects to 1400 subjects (700 per arm), in order to collect additional safety information; inclusion criterion 2 was updated to clarify that during the first season of the study, children with aortic stenosis, pulmonic lesions, or coarctation of the aorta alone were not eligible for the study, and to specify that children with acyanotic cardiac lesions must have had pulmonary hypertension or the need for daily medication to manage their CHD to be eligible for enrollment; details of randomization were revised; window for the Study Day 150 visit was changed from "Study Day 150(±7)" to "Study Day 150-157;" descriptions of hospitalizations were modifies to ensure that specimens for RSV detection were obtained from subjects when they were hospitalized at a hospital other than the study site, and indicate that RSV testing on respiratory secretions would be performed by central RT-PCR, and not by RSV antigen testing; congenital anomaly/birth defect was deleted from the definition of an SAE and listed cardiac/respiratory deteriorations under medical events to be reported as hospitalizations and SAEs.
20 April 2007	MI-CP124 (Season 2) amendment-1 included the following changes: section 'Preclinical Experience with Motavizumab' was updated with the overall results of a chronic toxicity study of motavizumab in cynomolgus monkeys; primary objectives were updated and 'secondary objectives' were added to evaluate the effect of motavizumab on rates of RSV-specific, medically-attended outpatient lower respiratory infection (LRI); exclusion criteria 11 was modified by removing palivizumab, RSV-IGIV, or other RSV-specific monoclonal antibody from the list of immunoglobulin products, not allowed to be taken within 3 months prior to enrollment and a new criteria was added for specifying that receipt of palivizumab within 3 months prior to enrollment was not allowed; "assessment of medically-attended LRI" was added to the schedule of events on Study Days 30, 60, 90, 120, and 150; sections 'Medically-Attended Lower Respiratory Tract Infection Episode and Definition of Serious Adverse Events' were updated; section 'Interruption or Discontinuation of Study Dosing in Individual Subjects' was revised by adding the following item to the list, "a severe or life- threatening serious systemic, allergic, or local reaction thought to be related to study drug" as a reason for interrupting or discontinuing study drug;" updated section 'Sample Size' with a discussion of the rationale for increasing the sample size and added Probability of Observing a Point Estimate of Relative Risk <1.0 to the protocol; added a fourth endpoint of "the incidence of RSV-specific, medically-attended outpatient LRI through Study Day 150;" replaced MEDI-524 by "motavizumab", where appropriate, throughout the protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported