



Clinical trial results:

A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody with an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)

Summary

EudraCT number	2019-000114-11
Trial protocol	BE LV GB SE FR DE CZ LT EE FI PL AT ES BG IT
Global end of trial date	20 June 2023

Results information

Result version number	v1 (current)
This version publication date	22 September 2023
First version publication date	22 September 2023

Trial information

Trial identification

Sponsor protocol code	D5290C00004
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	950 Wind River Ln, Gaithersburg, United States, MD 20878
Public contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001794-PIP01-15
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 June 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 June 2021
Global end of trial reached?	Yes
Global end of trial date	20 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of nirsevimab when administered as a single fixed IM dose to term/late preterm infants \geq 35 weeks 0 days GA and entering their first RSV season, in reducing MA RSV LRTI, compared to placebo

Protection of trial subjects:

Each subject was assigned a SID to ensure that personally identifiable information was kept separate from the study data. Subject data that were relevant to the trial, eg, demographic information, physical or mental health condition, diagnosis, comorbidities, laboratory test results, etc. were collected with the subject's informed consent.

The IRB/IEC responsible for each site must review and approve the final study protocol, including the final version of the Informed Consent Form and any other written information and/or materials to be provided to the subjects. The IRB/IEC must also approve all advertising used to recruit subjects for the study.

Before the study was initiated, AstraZeneca/MedImmune ensured that the national regulatory authority in each country had been notified and their approval had been obtained, as required.

AstraZeneca/MedImmune provided safety updates/reports according to local requirements, including suspected unexpected serious adverse reactions where relevant, to regulatory authorities, IRB/IEC, and principal investigators.

Background therapy:

MEDI8897 is a recombinant human immunoglobulin G1 kappa (IgG1 κ) monoclonal antibody (mAb) directed against the prefusion conformation of the RSV fusion (F) protein. The antibody has been engineered with a triple amino acid substitution (YTE; M257Y/S259T/T261E [M252Y/S254T/T256E, according to the European Union (EU) numbering system]) in the fragment crystallizable (Fc) region to prolong the t_{1/2}, which is expected to provide protection from serious RSV disease for the duration of the RSV season. MEDI8897 neutralizes RSV by binding the prefusion conformation of the RSV F protein at a site distinct from that bound by palivizumab. In preclinical studies, MEDI8897 was > 150 fold more potent than palivizumab in vitro and approximately 9-fold more potent than palivizumab in vivo in the cotton rat model. MEDI8897 is currently under development by MedImmune for the passive immunization of all infants entering their first RSV season and children with CLD or CHD entering their first and second RSV season for the prevention of LRTI caused by RSV. MEDI8897 may provide a cost effective opportunity to protect all infants from RSV disease based on an improvement in potency and the extended t_{1/2} that is expected to support once-per-RSV-season dosing.

Evidence for comparator: -

Actual start date of recruitment	23 July 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	17 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 8
Country: Number of subjects enrolled	Belgium: 14
Country: Number of subjects enrolled	Bulgaria: 131
Country: Number of subjects enrolled	Canada: 13
Country: Number of subjects enrolled	Czechia: 29
Country: Number of subjects enrolled	Estonia: 73
Country: Number of subjects enrolled	Finland: 44
Country: Number of subjects enrolled	France: 30
Country: Number of subjects enrolled	Germany: 58
Country: Number of subjects enrolled	Israel: 44
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Japan: 147
Country: Number of subjects enrolled	Korea, Republic of: 2
Country: Number of subjects enrolled	Latvia: 50
Country: Number of subjects enrolled	Lithuania: 57
Country: Number of subjects enrolled	Mexico: 1
Country: Number of subjects enrolled	Panama: 505
Country: Number of subjects enrolled	Poland: 58
Country: Number of subjects enrolled	Russian Federation: 93
Country: Number of subjects enrolled	Spain: 213
Country: Number of subjects enrolled	Sweden: 32
Country: Number of subjects enrolled	Turkey: 16
Country: Number of subjects enrolled	Ukraine: 34
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	United States: 558
Country: Number of subjects enrolled	Argentina: 178
Country: Number of subjects enrolled	Australia: 27
Country: Number of subjects enrolled	Chile: 45
Country: Number of subjects enrolled	Colombia: 54
Country: Number of subjects enrolled	New Zealand: 21
Country: Number of subjects enrolled	South Africa: 462
Worldwide total number of subjects	3012
EEA total number of subjects	804

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	655
Infants and toddlers (28 days-23 months)	2357
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:

The study was planned to recruit around 3000 infants. The impact of the COVID-19 pandemic on RSV circulation led to the decision to analyze the primary endpoint on the first 1500 subjects (Primary Cohort). Then the study restarted to recruit and the study comprised 2 cohorts: Primary and Safety for a total of 3319 screened subjects

Pre-assignment

Screening details:

In Primary Cohort: 1626 screened subjects and 136 subjects failing screening criteria.

Overall 3319 screened subjects and 307 subjects failing screening criteria.

Period 1

Period 1 title	All Subjects
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo
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Arm description:

Placebo in All Subjects

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Commercially available 0.9% (w/v) saline (sterile for human use)

Arm title	Medi9987
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Arm description:

Medi9987 in All Subjects

Arm type	Experimental
Investigational medicinal product name	Nirsevimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single IM dose of 50 mg (if < 5 kg weight at time of dosing) or 100 mg (if ≥ 5 kg weight at time of dosing)

Number of subjects in period 1	Placebo	Medi9987
Started	1003	2009
Completed Day 151 Follow up	985	1977
Completed Day 361 Follow up	967	1944
Completed	923	1873
Not completed	80	136
Adverse event, serious fatal	-	5
Consent withdrawn by subject	35	44
Other	16	23
Covid 19 Pandemic	1	3
Lost to follow-up	28	61

Period 2

Period 2 title	Primary Cohort
Is this the baseline period?	Yes ^[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo
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Arm description:

Placebo in Primary Cohort

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Commercially available 0.9% (w/v) saline (sterile for human use)

Arm title	Medi9987
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Arm description:

Medi9987 in Primary Cohort

Arm type	Experimental
Investigational medicinal product name	Nirsevimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single IM dose of 50 mg (if < 5 kg weight at time of

dosing) or 100 mg (if ≥ 5 kg weight at time of dosing)

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Primary cohort is the baseline period for the primary efficacy analysis

Number of subjects in period 2^[2][3]	Placebo	Medi9987
Started	496	994
Complete Day 151 Follow Up	488	977
Complete Day 361 Follow UP	453	914
Completed	43	89
Not completed	453	905
Adverse event, serious fatal	-	4
Consent withdrawn by subject	14	20
Other	3	4
Ongoing at the DCO	432	865
Covid 19 Pandemic	1	3
Lost to follow-up	3	9

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Primary cohort is a subset of the All subjects population

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Primary cohort is a subset of the All subjects population

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Placebo in Primary Cohort	
Reporting group title	Medi9987
Reporting group description: Medi9987 in Primary Cohort	

Reporting group values	Placebo	Medi9987	Total
Number of subjects	496	994	1490
Age Categorical			
Age in months at randomization in Primary Cohort			
Units: Subjects			
<= 3 months	285	577	862
> 3 months - <= 6 months	162	317	479
>= 6 months	49	100	149
Age Continuous			
Age (months) at randomization			
Units: months			
arithmetic mean	3.012	2.912	
standard deviation	± 2.2520	± 2.946	-
Gender Categorical			
Gender in the Primary Cohort			
Units: Subjects			
Male	239	530	769
Female	257	464	721

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Placebo in All Subjects	
Reporting group title	Medi9987
Reporting group description: Medi9987 in All Subjects	
Reporting group title	Placebo
Reporting group description: Placebo in Primary Cohort	
Reporting group title	Medi9987
Reporting group description: Medi9987 in Primary Cohort	

Primary: Incidence of MA RSV LRTI Through 150 Days Post Dose (Primary Cohort)

End point title	Incidence of MA RSV LRTI Through 150 Days Post Dose (Primary Cohort)
End point description: Primary Endpoint Analysed on Primary Cohort Through 150 Days (N=1490 Participants)	
End point type	Primary
End point timeframe: Through 150 Days Post Dose	

End point values	Placebo	Medi9987		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	496	994		
Units: Participants				
Observed events through day 150 post dose	25	12		
Subjects requiring imputation	6	15		
Subjects without event through day 150 post dose	465	967		

Statistical analyses

Statistical analysis title	Relative Risk Reduction Analysis
Statistical analysis description: Relative risk reduction of nirsevimab versus placebo, the 95% CI and p-value were estimated based on Poisson regression with robust variance (including stratification factor [age at randomisation] as covariate) obtained after missing data imputation.	
Comparison groups	Placebo v Medi9987

Number of subjects included in analysis	1490
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Poisson Model
Parameter estimate	Relative Risk Reduction
Point estimate	74.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.63
upper limit	87.12

Secondary: Incidence of MA RSV LRTI with Hospitalisation Through 150 Days Post Dose (Primary Cohort)

End point title	Incidence of MA RSV LRTI with Hospitalisation Through 150 Days Post Dose (Primary Cohort)
End point description:	
End point type	Secondary
End point timeframe:	
Hospitalization Analysed on Primary Cohort Through 150 Days (N=1490 Participants)	

End point values	Placebo	Medi9987		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	496	994		
Units: Participants				
Observed events through day 150 post dose	6	8		
Subjects requiring imputation	15	6		
Subjects without event through day 150 post dose	973	482		

Statistical analyses

Statistical analysis title	Relative Risk Reduction Analysis
Statistical analysis description:	
Relative risk reduction of nirsevimab versus placebo, the 95% CI and p-value were estimated based on Poisson regression with robust variance (including study as covariate for pooled studies) obtained after missing data imputation.	
Comparison groups	Medi9987 v Placebo

Number of subjects included in analysis	1490
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0708
Method	Poisson Regression Model
Parameter estimate	Relative Risk Reduction
Point estimate	62.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.57
upper limit	86.8

Other pre-specified: Disease Incidence from the 2nd RSV Season (All Subjects)

End point title	Disease Incidence from the 2nd RSV Season (All Subjects)
End point description:	
End point type	Other pre-specified
End point timeframe:	
From Day 361 to Day 510 Post Dose	

End point values	Placebo	Medi9987		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	967	1944		
Units: Participants				
MA RSV LRTI (protocol defined)	10	19		
MA RSV LRTI hospitalization (protocol defined)	3	3		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Incidence of MA RSV LRTI Through 150 Days Post Dose (All Subjects)

End point title	Incidence of MA RSV LRTI Through 150 Days Post Dose (All Subjects)
End point description:	
Primary Endpoint Analysed on All Subjects Through 150 Days (N=3012 participants)	
End point type	Post-hoc
End point timeframe:	
Through 150 Days Post Dose	

End point values	Placebo	Medi9987		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1003	2009		
Units: Participants				
Observed events	54	24		
Subjects requiring imputation	17	31		
Subjects without event through day 150 post dose	932	1954		

Statistical analyses

Statistical analysis title	Relative Risk Reduction Analysis
Statistical analysis description:	
Relative risk reduction of nirsevimab versus placebo, the 95% CI and p-value were estimated based on Poisson regression with robust variance (including stratification factor [age at randomisation] as covariate) obtained after missing data imputation.	
Comparison groups	Placebo v Medi9987
Number of subjects included in analysis	3012
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.0001
Method	Poisson regression model
Parameter estimate	Relative Risk Reduction (RRR)
Point estimate	76.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.27
upper limit	85.18

Post-hoc: Incidence of MA RSV LRTI with Hospitalisation Through 150 Days Post Dose (All Subjects)

End point title	Incidence of MA RSV LRTI with Hospitalisation Through 150 Days Post Dose (All Subjects)
End point description:	
Hospitalization Analysed on All Subjects Through 150 Days (N=3012 participants)	
End point type	Post-hoc
End point timeframe:	
Through 150 Days Post Dose	

End point values	Placebo	Medi9987		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1003	2009		
Units: Participants				
Observed events through day 150 post dose	20	9		
Subjects requiring imputation	18	31		
Subjects without event through day 150 post dose	965	1969		

Statistical analyses

Statistical analysis title	Relative Risk Reduction Analysis
Statistical analysis description:	
RRR of Medi8897 versus placebo; 95% CI and p-value estimated with Poisson regression with robust variance (including stratification factors [age at randomisation] as covariate) obtained after multiple imputation	
Comparison groups	Placebo v Medi9987
Number of subjects included in analysis	3012
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.0002
Method	Poisson model
Parameter estimate	Relative Risk Reduction (RRR)
Point estimate	76.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.36
upper limit	89.41

Adverse events

Adverse events information

Timeframe for reporting adverse events:
through 360 days post dose

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	MedDRA25.1

Reporting groups

Reporting group title	Placebo
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Reporting group description:
Placebo (All Subjects)

Reporting group title	MEDI8897
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Reporting group description:
MEDI8897 (All Subjects)

Serious adverse events	Placebo	MEDI8897	
Total subjects affected by serious adverse events			
subjects affected / exposed	83 / 997 (8.32%)	149 / 1997 (7.46%)	
number of deaths (all causes)	0	5	
number of deaths resulting from adverse events	0	4	
Vascular disorders			
Shock			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kawasaki's disease			
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
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			

Pyrexia			
subjects affected / exposed	1 / 997 (0.10%)	6 / 1997 (0.30%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fever neonatal			
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial hyperreactivity			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apnoea			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Staring			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep terror			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Behavioural insomnia of childhood			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fractured base			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Head injury			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
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 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Fall			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental exposure to product by child			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns third degree			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Pyloric stenosis			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phenylketonuria			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchogenic cyst			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 997 (0.00%)	4 / 1997 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic generalised epilepsy			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotonia			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Hypochromic anaemia			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			

subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (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	0 / 997 (0.00%)	3 / 1997 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Allergic gastroenteritis		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Allergic colitis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
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	0 / 997 (0.00%)	2 / 1997 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
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			
Petechiae			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Scoliosis			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess of external auditory meatus			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoviral upper respiratory infection			
subjects affected / exposed	0 / 997 (0.00%)	3 / 1997 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Botulism			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	17 / 997 (1.71%)	27 / 1997 (1.35%)	
occurrences causally related to treatment / all	0 / 18	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	

COVID-19			
subjects affected / exposed	2 / 997 (0.20%)	3 / 1997 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis viral			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	4 / 997 (0.40%)	3 / 1997 (0.15%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis viral			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovirus infection			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia pyelonephritis			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exanthema subitum			

subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	5 / 997 (0.50%)	14 / 1997 (0.70%)
occurrences causally related to treatment / all	0 / 5	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 2
Gastroenteritis Escherichia coli		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis adenovirus		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis rotavirus		
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hand-foot-and-mouth disease		

subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Impetigo		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		
subjects affected / exposed	3 / 997 (0.30%)	3 / 1997 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	0 / 997 (0.00%)	6 / 1997 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media acute		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
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 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngitis		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection viral		

subjects affected / exposed	1 / 997 (0.10%)	3 / 1997 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pertussis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngotonsillitis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	5 / 997 (0.50%)	13 / 1997 (0.65%)
occurrences causally related to treatment / all	0 / 5	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia respiratory syncytial viral		
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		

subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
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	10 / 997 (1.00%)	5 / 1997 (0.25%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus bronchitis		
subjects affected / exposed	2 / 997 (0.20%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal abscess		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal scalded skin syndrome		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		
subjects affected / exposed	2 / 997 (0.20%)	0 / 1997 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		

subjects affected / exposed	5 / 997 (0.50%)	7 / 1997 (0.35%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 997 (0.20%)	4 / 1997 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	2 / 997 (0.20%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 997 (0.00%)	4 / 1997 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dairy intolerance			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			

subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food refusal			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	MEDI8897	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	836 / 997 (83.85%)	1717 / 1997 (85.98%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cartilage neoplasm			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences (all)	0	1	
Haemangioma			
subjects affected / exposed	1 / 997 (0.10%)	9 / 1997 (0.45%)	
occurrences (all)	2	9	
Haemangioma of skin			
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)	
occurrences (all)	1	2	
Lipoma			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences (all)	1	0	
Melanocytic naevus			
subjects affected / exposed	0 / 997 (0.00%)	3 / 1997 (0.15%)	
occurrences (all)	0	3	
Pyogenic granuloma			

subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Skin papilloma subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2	
Vascular disorders			
Cyanosis subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	3 / 1997 (0.15%) 3	
Pallor subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Phlebitis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Surgical and medical procedures			
Clamping of blood vessel subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Circumcision subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	4 / 1997 (0.20%) 4	
Infection prophylaxis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Scrotal operation subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Skin lesion removal subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 2	
Urethral repair subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Oral surgery			

subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Small for dates baby subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Umbilical granuloma subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	1 / 1997 (0.05%) 1	
General disorders and administration site conditions			
Secretion discharge subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Asthenia subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1	
Crying subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Developmental delay subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	3 / 1997 (0.15%) 3	
Discomfort subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	10 / 1997 (0.50%) 10	
Fatigue subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Gait disturbance subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Hypothermia			

subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Influenza like illness		
subjects affected / exposed	4 / 997 (0.40%)	2 / 1997 (0.10%)
occurrences (all)	4	2
Injection site induration		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Injection site pain		
subjects affected / exposed	0 / 997 (0.00%)	4 / 1997 (0.20%)
occurrences (all)	0	4
Injection site swelling		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Malaise		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Mass		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
PFAPA syndrome		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Pain		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Peripheral swelling		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Pyrexia		
subjects affected / exposed	122 / 997 (12.24%)	290 / 1997 (14.52%)
occurrences (all)	165	378
Vaccination site erythema		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2

Vaccination site reaction subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Vaccination site swelling subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Vessel puncture site haemorrhage subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Xerosis subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	5 / 1997 (0.25%) 6	
Vaccination site pain subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	3 / 1997 (0.15%) 5	
Immune system disorders			
Allergy to animal subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Allergy to arthropod bite subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	6 / 1997 (0.30%) 6	
Anaphylactic reaction subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Drug hypersensitivity subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	9 / 1997 (0.45%) 9	
Dust allergy subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Food allergy subjects affected / exposed occurrences (all)	18 / 997 (1.81%) 22	30 / 1997 (1.50%) 36	
Hypersensitivity			

subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	1 / 1997 (0.05%) 1	
Milk allergy subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 7	7 / 1997 (0.35%) 7	
Multiple allergies subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2	
Reaction to preservatives subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Seasonal allergy subjects affected / exposed occurrences (all)	6 / 997 (0.60%) 6	8 / 1997 (0.40%) 8	
Reproductive system and breast disorders			
Genital discomfort subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Acquired hydrocele subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	3 / 1997 (0.15%) 3	
Balanoposthitis subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	6 / 1997 (0.30%) 6	
Breast cyst subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Breast enlargement subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Genital labial adhesions subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	3 / 1997 (0.15%) 3	
Genital ulceration			

subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Penile adhesion subjects affected / exposed occurrences (all)	5 / 997 (0.50%) 5	6 / 1997 (0.30%) 6	
Penile discharge subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Penile erythema subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Testicular mass subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Vaginal discharge subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Vulvovaginal adhesion subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Vulvovaginal erythema subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Genital pain subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Respiratory failure subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Respiration abnormal subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	2 / 1997 (0.10%) 2	
Rhinitis allergic			

subjects affected / exposed occurrences (all)	12 / 997 (1.20%) 15	13 / 1997 (0.65%) 14
Aphonia subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2
Asthma subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	4 / 1997 (0.20%) 6
Brief resolved unexplained event subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Bronchial hyperreactivity subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	3 / 1997 (0.15%) 3
Bronchial obstruction subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	4 / 1997 (0.20%) 5
Bronchospasm subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2
Catarrh subjects affected / exposed occurrences (all)	8 / 997 (0.80%) 12	13 / 1997 (0.65%) 13
Childhood asthma subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Choking subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2
Cough subjects affected / exposed occurrences (all)	58 / 997 (5.82%) 69	115 / 1997 (5.76%) 145
Dysphonia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Epistaxis		

subjects affected / exposed	0 / 997 (0.00%)	4 / 1997 (0.20%)
occurrences (all)	0	7
Hiccups		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Nasal congestion		
subjects affected / exposed	86 / 997 (8.63%)	164 / 1997 (8.21%)
occurrences (all)	113	208
Nasal obstruction		
subjects affected / exposed	5 / 997 (0.50%)	18 / 1997 (0.90%)
occurrences (all)	7	19
Oropharyngeal pain		
subjects affected / exposed	2 / 997 (0.20%)	3 / 1997 (0.15%)
occurrences (all)	2	3
Pharyngeal inflammation		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Pneumothorax		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Productive cough		
subjects affected / exposed	2 / 997 (0.20%)	1 / 1997 (0.05%)
occurrences (all)	2	1
Rhinalgia		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Rhinorrhoea		
subjects affected / exposed	65 / 997 (6.52%)	152 / 1997 (7.61%)
occurrences (all)	85	216
Sinus congestion		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Sleep apnoea syndrome		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Sneezing		

subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	5 / 1997 (0.25%) 5
Snoring		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Stridor		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Tachypnoea		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Throat irritation		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Tracheomalacia		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Upper airway obstruction		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Upper respiratory tract congestion		
subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	7 / 1997 (0.35%) 8
Upper respiratory tract inflammation		
subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 3	6 / 1997 (0.30%) 11
Upper respiratory tract irritation		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Vasomotor rhinitis		
subjects affected / exposed occurrences (all)	5 / 997 (0.50%) 5	12 / 1997 (0.60%) 15
Wheezing		
subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 4	5 / 1997 (0.25%) 5
Psychiatric disorders		

Sleep disorder subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	3 / 1997 (0.15%) 3	
Anxiety subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	3 / 1997 (0.15%) 3	
Irritability subjects affected / exposed occurrences (all)	11 / 997 (1.10%) 11	22 / 1997 (1.10%) 26	
Poor quality sleep subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Restlessness subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Jaundice subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	7 / 1997 (0.35%) 7	
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Body temperature increased subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	5 / 1997 (0.25%) 5	
Blood immunoglobulin E increased subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Blood lead increased			

subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Blood copper increased subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Cardiac murmur subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 4	5 / 1997 (0.25%) 5
Cardiac murmur functional subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Echocardiogram abnormal subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Platelet count increased subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Liver function test abnormal subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Medical observation normal subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Neutrophil count decreased subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	0 / 1997 (0.00%) 0
Haemoglobin decreased subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
SARS-CoV-2 test negative subjects affected / exposed occurrences (all)	27 / 997 (2.71%) 30	48 / 1997 (2.40%) 58
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 4	3 / 1997 (0.15%) 3
Transaminases increased		

subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Urine analysis abnormal subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Injury, poisoning and procedural complications			
Corneal abrasion subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Animal bite subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Animal scratch subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Arthropod bite subjects affected / exposed occurrences (all)	22 / 997 (2.21%) 24	27 / 1997 (1.35%) 31	
Arthropod sting subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	2 / 1997 (0.10%) 2	
Bone contusion subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Brain contusion subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Burns first degree subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2	
Burns second degree subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1	
Chemical burn			

subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Concussion		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Contusion		
subjects affected / exposed	3 / 997 (0.30%)	11 / 1997 (0.55%)
occurrences (all)	3	11
Craniocerebral injury		
subjects affected / exposed	2 / 997 (0.20%)	6 / 1997 (0.30%)
occurrences (all)	2	6
Post procedural erythema		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Eye contusion		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Eye injury		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Eyelid injury		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Face injury		
subjects affected / exposed	2 / 997 (0.20%)	3 / 1997 (0.15%)
occurrences (all)	2	3
Fall		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Femur fracture		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Foreign body in ear		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Foreign body in eye		

subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Foreign body in gastrointestinal tract		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Foreign body in respiratory tract		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Foreign body in throat		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Foreign body ingestion		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Gingival injury		
subjects affected / exposed	1 / 997 (0.10%)	4 / 1997 (0.20%)
occurrences (all)	1	4
Hand fracture		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Head injury		
subjects affected / exposed	6 / 997 (0.60%)	16 / 1997 (0.80%)
occurrences (all)	7	17
Injury		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	2
Limb injury		
subjects affected / exposed	3 / 997 (0.30%)	3 / 1997 (0.15%)
occurrences (all)	3	3
Lip injury		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Mouth injury		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Multiple injuries		

subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Muscle contusion		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Nail injury		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Nasal injury		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Oral contusion		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Exposure to toxic agent		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Post procedural haemorrhage		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Postoperative ileus		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Procedural pain		
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences (all)	1	2
Radial head dislocation		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Road traffic accident		
subjects affected / exposed	0 / 997 (0.00%)	3 / 1997 (0.15%)
occurrences (all)	0	3
Scratch		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Skin abrasion		

subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	8 / 1997 (0.40%) 8
Skin injury subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Skin laceration subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Skull fracture subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Thermal burn subjects affected / exposed occurrences (all)	5 / 997 (0.50%) 5	10 / 1997 (0.50%) 11
Tibia fracture subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Tooth fracture subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Tooth injury subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Traumatic haematoma subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Vaccination complication subjects affected / exposed occurrences (all)	34 / 997 (3.41%) 47	72 / 1997 (3.61%) 90
Vulvovaginal injury subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Post-traumatic pain subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Congenital, familial and genetic		

disorders		
Bronchogenic cyst		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Aorta hypoplasia		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Atrial septal defect		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Brachycephaly		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Buried penis syndrome		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Telangiectasia congenital		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Congenital nystagmus		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Congenital tongue anomaly		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Congenital torticollis		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Congenital vesicoureteric reflux		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Cryptorchism		
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences (all)	1	2
Dacryostenosis congenital		

subjects affected / exposed	3 / 997 (0.30%)	16 / 1997 (0.80%)
occurrences (all)	3	16
Dermoid cyst		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Developmental hip dysplasia		
subjects affected / exposed	4 / 997 (0.40%)	4 / 1997 (0.20%)
occurrences (all)	4	4
Hydrocele		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Klippel-Feil syndrome		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Laryngomalacia		
subjects affected / exposed	0 / 997 (0.00%)	4 / 1997 (0.20%)
occurrences (all)	0	4
Macrocephaly		
subjects affected / exposed	2 / 997 (0.20%)	0 / 1997 (0.00%)
occurrences (all)	2	0
Mitochondrial encephalomyopathy		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Patent ductus arteriosus		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Phimosis		
subjects affected / exposed	0 / 997 (0.00%)	3 / 1997 (0.15%)
occurrences (all)	0	3
Plagiocephaly		
subjects affected / exposed	4 / 997 (0.40%)	11 / 1997 (0.55%)
occurrences (all)	4	11
Talipes		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Congenital anomaly		

subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Vascular malformation subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Ventricular septal defect subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Cardiac disorders			
Left ventricular hypertrophy subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Supraventricular extrasystoles subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Tachycardia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Nervous system disorders			
Chorea subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Febrile convulsion subjects affected / exposed occurrences (all)	5 / 997 (0.50%) 5	4 / 1997 (0.20%) 4	
Gross motor delay subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	3 / 1997 (0.15%) 3	
Head discomfort subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Horner's syndrome			

subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Hypertonia		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Hypotonia		
subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	1 / 1997 (0.05%) 1
Idiopathic partial epilepsy		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Motor developmental delay		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Nystagmus		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Post-traumatic epilepsy		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Psychomotor skills impaired		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Seizure		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Seizure like phenomena		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Somnolence		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2
Speech disorder developmental		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	3 / 1997 (0.15%) 3
Tremor		

subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	3 / 1997 (0.15%) 3	
Infant irritability subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 4	1 / 1997 (0.05%) 1	
Blood and lymphatic system disorders			
Lymphadenitis subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	3 / 1997 (0.15%) 3	
Leukocytosis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Microcytic anaemia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Neutropenia subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	2 / 1997 (0.10%) 2	
Normochromic normocytic anaemia subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Thrombocytosis subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Anaemia subjects affected / exposed occurrences (all)	8 / 997 (0.80%) 8	13 / 1997 (0.65%) 13	
Anaemia neonatal subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	3 / 1997 (0.15%) 3	
Hypochromic anaemia subjects affected / exposed occurrences (all)	7 / 997 (0.70%) 8	13 / 1997 (0.65%) 13	

Iron deficiency anaemia subjects affected / exposed occurrences (all)	8 / 997 (0.80%) 8	14 / 1997 (0.70%) 14	
Lymphadenopathy subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	7 / 1997 (0.35%) 7	
Ear and labyrinth disorders			
Cerumen impaction subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1	
Deafness neurosensory subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Ear pain subjects affected / exposed occurrences (all)	7 / 997 (0.70%) 8	12 / 1997 (0.60%) 14	
Excessive cerumen production subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Middle ear effusion subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1	
Motion sickness subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 3	
Otorrhoea subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1	
Tympanic membrane hyperaemia subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	0 / 1997 (0.00%) 0	
Eye disorders			
Eye swelling subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Astigmatism			

subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Blepharitis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Cataract subcapsular		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Conjunctival haemorrhage		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Conjunctival hyperaemia		
subjects affected / exposed	2 / 997 (0.20%)	0 / 1997 (0.00%)
occurrences (all)	2	0
Conjunctivitis allergic		
subjects affected / exposed	2 / 997 (0.20%)	6 / 1997 (0.30%)
occurrences (all)	2	6
Dacryostenosis acquired		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Erythema of eyelid		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Eye discharge		
subjects affected / exposed	2 / 997 (0.20%)	6 / 1997 (0.30%)
occurrences (all)	2	6
Pseudostrabismus		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Periorbital oedema		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Pupillary disorder		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Strabismus		

subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	3 / 1997 (0.15%) 3	
Swelling of eyelid subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Eyelid oedema subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Hypermetropia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Keratitis subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Lacrimal structural disorder subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Lacrimation increased subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	4 / 1997 (0.20%) 4	
Pterygium subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Gastrointestinal disorders			
Abdominal distension subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	5 / 1997 (0.25%) 5	
Abdominal mass subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Abdominal pain subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	2 / 1997 (0.10%) 2	

Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	3 / 1997 (0.15%) 3
Abdominal tenderness subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Aerophagia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Anal fissure subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	6 / 1997 (0.30%) 6
Anal polyp subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Angular cheilitis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Infantile colic subjects affected / exposed occurrences (all)	11 / 997 (1.10%) 13	41 / 1997 (2.05%) 41
Auriculotemporal syndrome subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Cheilitis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Constipation subjects affected / exposed occurrences (all)	38 / 997 (3.81%) 42	88 / 1997 (4.41%) 96
Diarrhoea subjects affected / exposed occurrences (all)	89 / 997 (8.93%) 104	171 / 1997 (8.56%) 196
Dyspepsia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2

Enteritis		
subjects affected / exposed	0 / 997 (0.00%)	3 / 1997 (0.15%)
occurrences (all)	0	3
Enterocolitis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Epulis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Faecaloma		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Faeces discoloured		
subjects affected / exposed	2 / 997 (0.20%)	1 / 1997 (0.05%)
occurrences (all)	2	1
Faeces soft		
subjects affected / exposed	2 / 997 (0.20%)	3 / 1997 (0.15%)
occurrences (all)	2	3
Flatulence		
subjects affected / exposed	4 / 997 (0.40%)	13 / 1997 (0.65%)
occurrences (all)	4	13
Food protein-induced enterocolitis syndrome		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Gastritis		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Gastritis erosive		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Gastrooesophageal reflux disease		
subjects affected / exposed	14 / 997 (1.40%)	31 / 1997 (1.55%)
occurrences (all)	14	32
Gingival cyst		

subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Gingival discomfort		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Gingival pain		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	3	0
Haematemesis		
subjects affected / exposed	0 / 997 (0.00%)	3 / 1997 (0.15%)
occurrences (all)	0	3
Haematochezia		
subjects affected / exposed	5 / 997 (0.50%)	2 / 1997 (0.10%)
occurrences (all)	6	2
Infant dyschezia		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Aphthous ulcer		
subjects affected / exposed	2 / 997 (0.20%)	2 / 1997 (0.10%)
occurrences (all)	2	2
Vomiting		
subjects affected / exposed	32 / 997 (3.21%)	59 / 1997 (2.95%)
occurrences (all)	35	63
Umbilical hernia		
subjects affected / exposed	4 / 997 (0.40%)	14 / 1997 (0.70%)
occurrences (all)	4	14
Infantile spitting up		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Inguinal hernia		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Lip ulceration		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Melaena		

subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Mouth ulceration subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Mucous stools subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Oesophageal perforation subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Oral mucosal eruption subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Regurgitation subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Stomatitis subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 4	7 / 1997 (0.35%) 7	
Teething subjects affected / exposed occurrences (all)	70 / 997 (7.02%) 85	138 / 1997 (6.91%) 171	
Toothache subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	6 / 1997 (0.30%) 12	
Skin and subcutaneous tissue disorders			
Acne infantile subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	4 / 1997 (0.20%) 4	
Asteatosis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	4 / 1997 (0.20%) 4	
Blister subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1	

Cafe au lait spots		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Dandruff		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Dermatitis		
subjects affected / exposed	21 / 997 (2.11%)	44 / 1997 (2.20%)
occurrences (all)	22	44
Dermatitis allergic		
subjects affected / exposed	5 / 997 (0.50%)	11 / 1997 (0.55%)
occurrences (all)	5	12
Dermatitis atopic		
subjects affected / exposed	25 / 997 (2.51%)	56 / 1997 (2.80%)
occurrences (all)	28	59
Dermatitis contact		
subjects affected / exposed	16 / 997 (1.60%)	39 / 1997 (1.95%)
occurrences (all)	18	41
Dermatitis diaper		
subjects affected / exposed	103 / 997 (10.33%)	224 / 1997 (11.22%)
occurrences (all)	118	267
Petechiae		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Drug eruption		
subjects affected / exposed	3 / 997 (0.30%)	4 / 1997 (0.20%)
occurrences (all)	3	4
Dry skin		
subjects affected / exposed	19 / 997 (1.91%)	39 / 1997 (1.95%)
occurrences (all)	19	41
Dyshidrotic eczema		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Eczema		

subjects affected / exposed	52 / 997 (5.22%)	90 / 1997 (4.51%)
occurrences (all)	59	98
Eczema asteatotic		
subjects affected / exposed	1 / 997 (0.10%)	6 / 1997 (0.30%)
occurrences (all)	1	6
Eczema infantile		
subjects affected / exposed	9 / 997 (0.90%)	21 / 1997 (1.05%)
occurrences (all)	11	23
Eczema nummular		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Ephelides		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Erythema		
subjects affected / exposed	4 / 997 (0.40%)	3 / 1997 (0.15%)
occurrences (all)	4	3
Erythema toxicum neonatorum		
subjects affected / exposed	3 / 997 (0.30%)	5 / 1997 (0.25%)
occurrences (all)	3	5
Haemorrhage subcutaneous		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Hand dermatitis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Idiopathic urticaria		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Ingrowing nail		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Intertrigo		
subjects affected / exposed	4 / 997 (0.40%)	2 / 1997 (0.10%)
occurrences (all)	4	2
Keratosis pilaris		

subjects affected / exposed	2 / 997 (0.20%)	5 / 1997 (0.25%)
occurrences (all)	2	5
Lichen striatus		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Macule		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Miliaria		
subjects affected / exposed	37 / 997 (3.71%)	60 / 1997 (3.00%)
occurrences (all)	47	71
Nail discolouration		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Neurodermatitis		
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences (all)	1	2
Papule		
subjects affected / exposed	2 / 997 (0.20%)	2 / 1997 (0.10%)
occurrences (all)	2	2
Perioral dermatitis		
subjects affected / exposed	2 / 997 (0.20%)	0 / 1997 (0.00%)
occurrences (all)	2	0
Dermatosis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Pityriasis rosea		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Post inflammatory pigmentation change		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Prurigo		
subjects affected / exposed	3 / 997 (0.30%)	6 / 1997 (0.30%)
occurrences (all)	3	6

Rash		
subjects affected / exposed	48 / 997 (4.81%)	93 / 1997 (4.66%)
occurrences (all)	55	108
Rash erythematous		
subjects affected / exposed	1 / 997 (0.10%)	3 / 1997 (0.15%)
occurrences (all)	1	3
Rash macular		
subjects affected / exposed	3 / 997 (0.30%)	2 / 1997 (0.10%)
occurrences (all)	3	2
Rash maculo-papular		
subjects affected / exposed	8 / 997 (0.80%)	17 / 1997 (0.85%)
occurrences (all)	8	17
Rash papular		
subjects affected / exposed	8 / 997 (0.80%)	15 / 1997 (0.75%)
occurrences (all)	8	15
Rash pruritic		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Seborrhoea		
subjects affected / exposed	1 / 997 (0.10%)	3 / 1997 (0.15%)
occurrences (all)	1	3
Seborrhoeic dermatitis		
subjects affected / exposed	17 / 997 (1.71%)	40 / 1997 (2.00%)
occurrences (all)	17	40
Skin exfoliation		
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences (all)	1	2
Skin hypopigmentation		
subjects affected / exposed	2 / 997 (0.20%)	6 / 1997 (0.30%)
occurrences (all)	2	6
Skin irritation		
subjects affected / exposed	3 / 997 (0.30%)	15 / 1997 (0.75%)
occurrences (all)	3	18
Thermal burn		
subjects affected / exposed	5 / 997 (0.50%)	10 / 1997 (0.50%)
occurrences (all)	5	11

Toxic skin eruption subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Transient neonatal pustular melanosis subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	0 / 1997 (0.00%) 0	
Urticaria subjects affected / exposed occurrences (all)	9 / 997 (0.90%) 11	21 / 1997 (1.05%) 25	
Urticaria chronic subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Urticaria contact subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 2	0 / 1997 (0.00%) 0	
Xeroderma subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Pityriasis alba subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 4	10 / 1997 (0.50%) 10	
Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Vesicoureteric reflux subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Dysuria subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	0 / 1997 (0.00%) 0	
Musculoskeletal and connective tissue disorders			

Foot deformity		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Diastasis recti abdominis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Acquired plagiocephaly		
subjects affected / exposed	3 / 997 (0.30%)	3 / 1997 (0.15%)
occurrences (all)	3	3
Arthropathy		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Growth retardation		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Head deformity		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Limb discomfort		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Musculoskeletal pain		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Posture abnormal		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Rib deformity		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Scoliosis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Torticollis		
subjects affected / exposed	1 / 997 (0.10%)	3 / 1997 (0.15%)
occurrences (all)	1	3

Haematoma muscle subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1	
Infections and infestations			
Abscess subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	2 / 1997 (0.10%) 2	
Abscess jaw subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0	
Abscess limb subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	2 / 1997 (0.10%) 2	
Abscess neck subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1	
Acarodermatitis subjects affected / exposed occurrences (all)	15 / 997 (1.50%) 20	32 / 1997 (1.60%) 39	
Acute sinusitis subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	2 / 1997 (0.10%) 2	
Adenoviral upper respiratory infection subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	6 / 1997 (0.30%) 6	
Adenovirus infection subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	1 / 1997 (0.05%) 1	
Amoebiasis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	3 / 1997 (0.15%) 3	
Amoebic dysentery subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2	
Anal abscess			

subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Ascariasis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Asymptomatic COVID-19 subjects affected / exposed occurrences (all)	7 / 997 (0.70%) 8	8 / 1997 (0.40%) 8
Bacterial disease carrier subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Body tinea subjects affected / exposed occurrences (all)	12 / 997 (1.20%) 14	20 / 1997 (1.00%) 22
Borrelia infection subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Bronchiolitis subjects affected / exposed occurrences (all)	71 / 997 (7.12%) 86	119 / 1997 (5.96%) 139
Bronchitis subjects affected / exposed occurrences (all)	31 / 997 (3.11%) 34	60 / 1997 (3.00%) 76
Bronchitis viral subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 3	1 / 1997 (0.05%) 1
Bullous impetigo subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	5 / 1997 (0.25%) 5
COVID-19 subjects affected / exposed occurrences (all)	59 / 997 (5.92%) 62	97 / 1997 (4.86%) 98
Candida infection subjects affected / exposed occurrences (all)	5 / 997 (0.50%) 5	4 / 1997 (0.20%) 5
Candida nappy rash		

subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	19 / 1997 (0.95%) 19
Cellulitis		
subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	6 / 1997 (0.30%) 6
Citrobacter infection		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Conjunctivitis		
subjects affected / exposed occurrences (all)	56 / 997 (5.62%) 61	137 / 1997 (6.86%) 157
Conjunctivitis bacterial		
subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 3	6 / 1997 (0.30%) 6
Conjunctivitis viral		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	3 / 1997 (0.15%) 3
Croup infectious		
subjects affected / exposed occurrences (all)	7 / 997 (0.70%) 7	17 / 1997 (0.85%) 18
Gastroenteritis viral		
subjects affected / exposed occurrences (all)	8 / 997 (0.80%) 11	21 / 1997 (1.05%) 23
Dacryocanaliculitis		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Dacryocystitis		
subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	2 / 1997 (0.10%) 2
Dermatitis infected		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Dermatophytosis		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Diarrhoea infectious		

subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Dysentery subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	1 / 1997 (0.05%) 1
Ear infection subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 5	4 / 1997 (0.20%) 4
Ear infection bacterial subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Ear lobe infection subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Eczema infected subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2
Enterobiasis subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Enterovirus infection subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	4 / 1997 (0.20%) 5
Exanthema subitum subjects affected / exposed occurrences (all)	27 / 997 (2.71%) 27	30 / 1997 (1.50%) 30
Eye infection subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	7 / 1997 (0.35%) 9
Febrile infection subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2
Folliculitis subjects affected / exposed occurrences (all)	4 / 997 (0.40%) 4	14 / 1997 (0.70%) 15
Fungal infection		

subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences (all)	1	2
Fungal skin infection		
subjects affected / exposed	19 / 997 (1.91%)	35 / 1997 (1.75%)
occurrences (all)	19	37
Furuncle		
subjects affected / exposed	1 / 997 (0.10%)	3 / 1997 (0.15%)
occurrences (all)	1	3
Gastroenteritis		
subjects affected / exposed	100 / 997 (10.03%)	202 / 1997 (10.12%)
occurrences (all)	113	246
Gastroenteritis adenovirus		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Gastroenteritis bacterial		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Gastroenteritis enteroviral		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Gastroenteritis rotavirus		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Cystitis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Joint abscess		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Influenza		
subjects affected / exposed	1 / 997 (0.10%)	9 / 1997 (0.45%)
occurrences (all)	1	10
Lice infestation		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1

Lower respiratory tract infection subjects affected / exposed occurrences (all)	34 / 997 (3.41%) 44	47 / 1997 (2.35%) 69
Lower respiratory tract infection viral subjects affected / exposed occurrences (all)	12 / 997 (1.20%) 12	9 / 1997 (0.45%) 9
Lyme disease subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Measles subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Mediastinitis subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Meningitis aseptic subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Metapneumovirus infection subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Gastrointestinal infection subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 2
Gastrointestinal viral infection subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	3 / 1997 (0.15%) 3
Genital candidiasis subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2
Genital infection fungal subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Gianotti-Crosti syndrome subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1

Hand-foot-and-mouth disease subjects affected / exposed occurrences (all)	19 / 997 (1.91%) 19	42 / 1997 (2.10%) 43
Helminthic infection subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Herpangina subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	5 / 1997 (0.25%) 5
Herpes ophthalmic subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Hordeolum subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	5 / 1997 (0.25%) 5
Human herpesvirus 6 infection subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Impetigo subjects affected / exposed occurrences (all)	31 / 997 (3.11%) 35	43 / 1997 (2.15%) 47
Infected bite subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Infected dermal cyst subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Infected skin ulcer subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Infection subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Laryngitis subjects affected / exposed occurrences (all)	9 / 997 (0.90%) 9	35 / 1997 (1.75%) 37

Molluscum contagiosum		
subjects affected / exposed	1 / 997 (0.10%)	9 / 1997 (0.45%)
occurrences (all)	1	10
Pyoderma streptococcal		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Omphalitis		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Oral candidiasis		
subjects affected / exposed	22 / 997 (2.21%)	55 / 1997 (2.75%)
occurrences (all)	23	60
Oral fungal infection		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Oral herpes		
subjects affected / exposed	1 / 997 (0.10%)	4 / 1997 (0.20%)
occurrences (all)	1	4
Oral infection		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Otitis externa		
subjects affected / exposed	6 / 997 (0.60%)	6 / 1997 (0.30%)
occurrences (all)	6	6
Otitis media		
subjects affected / exposed	76 / 997 (7.62%)	154 / 1997 (7.71%)
occurrences (all)	111	218
Otitis media acute		
subjects affected / exposed	44 / 997 (4.41%)	82 / 1997 (4.11%)
occurrences (all)	53	126
Otitis media chronic		
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences (all)	2	2
Parasitic gastroenteritis		
subjects affected / exposed	2 / 997 (0.20%)	4 / 1997 (0.20%)
occurrences (all)	2	4

Paronychia		
subjects affected / exposed	2 / 997 (0.20%)	11 / 1997 (0.55%)
occurrences (all)	2	12
Periorbital cellulitis		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Pertussis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Pharyngitis		
subjects affected / exposed	28 / 997 (2.81%)	72 / 1997 (3.61%)
occurrences (all)	28	80
Pharyngitis streptococcal		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Pharyngotonsillitis		
subjects affected / exposed	9 / 997 (0.90%)	16 / 1997 (0.80%)
occurrences (all)	9	16
Pneumonia		
subjects affected / exposed	6 / 997 (0.60%)	11 / 1997 (0.55%)
occurrences (all)	6	11
Pneumonia bacterial		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Pneumonia moraxella		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Pulmonary tuberculosis		
subjects affected / exposed	1 / 997 (0.10%)	1 / 1997 (0.05%)
occurrences (all)	1	1
Pustule		
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)
occurrences (all)	1	2
Pyelonephritis		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0

Pyoderma		
subjects affected / exposed	1 / 997 (0.10%)	3 / 1997 (0.15%)
occurrences (all)	1	3
Nasopharyngitis		
subjects affected / exposed	237 / 997 (23.77%)	441 / 1997 (22.08%)
occurrences (all)	471	946
Rash pustular		
subjects affected / exposed	0 / 997 (0.00%)	2 / 1997 (0.10%)
occurrences (all)	0	2
Upper respiratory tract infection		
subjects affected / exposed	316 / 997 (31.70%)	639 / 1997 (32.00%)
occurrences (all)	621	1316
Respiratory syncytial virus bronchitis		
subjects affected / exposed	3 / 997 (0.30%)	0 / 1997 (0.00%)
occurrences (all)	3	0
Respiratory syncytial virus infection		
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)
occurrences (all)	1	0
Respiratory tract infection		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Respiratory tract infection viral		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Rhinitis		
subjects affected / exposed	102 / 997 (10.23%)	201 / 1997 (10.07%)
occurrences (all)	146	272
Rhinolaryngitis		
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)
occurrences (all)	0	1
Roseola		
subjects affected / exposed	14 / 997 (1.40%)	24 / 1997 (1.20%)
occurrences (all)	14	24
Scarlet fever		

subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Sinusitis		
subjects affected / exposed occurrences (all)	7 / 997 (0.70%) 7	9 / 1997 (0.45%) 9
Sinusitis bacterial		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Skin bacterial infection		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Skin candida		
subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	9 / 1997 (0.45%) 9
Skin infection		
subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 3	2 / 1997 (0.10%) 2
Subcutaneous abscess		
subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	2 / 1997 (0.10%) 2
Subglottic laryngitis		
subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 3	1 / 1997 (0.05%) 1
Suspected COVID-19		
subjects affected / exposed occurrences (all)	7 / 997 (0.70%) 7	10 / 1997 (0.50%) 10
Tinea capitis		
subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	1 / 1997 (0.05%) 1
Tinea cruris		
subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	0 / 1997 (0.00%) 0
Tinea infection		
subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	4 / 1997 (0.20%) 4
Tinea pedis		

subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Tinea versicolour subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Tonsillitis subjects affected / exposed occurrences (all)	7 / 997 (0.70%) 7	14 / 1997 (0.70%) 15
Tracheitis subjects affected / exposed occurrences (all)	2 / 997 (0.20%) 2	4 / 1997 (0.20%) 4
Tracheobronchitis subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	2 / 1997 (0.10%) 2
Respiratory syncytial virus bronchiolitis subjects affected / exposed occurrences (all)	14 / 997 (1.40%) 14	13 / 1997 (0.65%) 13
Urinary tract infection subjects affected / exposed occurrences (all)	14 / 997 (1.40%) 15	22 / 1997 (1.10%) 26
Vaccination site infection subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Varicella subjects affected / exposed occurrences (all)	10 / 997 (1.00%) 10	22 / 1997 (1.10%) 22
Varicella zoster virus infection subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	2 / 1997 (0.10%) 2
Viral diarrhoea subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Viral infection subjects affected / exposed occurrences (all)	21 / 997 (2.11%) 22	35 / 1997 (1.75%) 36

Viral pharyngitis			
subjects affected / exposed	2 / 997 (0.20%)	9 / 1997 (0.45%)	
occurrences (all)	2	9	
Viral rash			
subjects affected / exposed	30 / 997 (3.01%)	85 / 1997 (4.26%)	
occurrences (all)	32	90	
Viral rhinitis			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences (all)	0	1	
Viral tonsillitis			
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)	
occurrences (all)	1	2	
Viral upper respiratory tract infection			
subjects affected / exposed	60 / 997 (6.02%)	132 / 1997 (6.61%)	
occurrences (all)	77	162	
Wound infection			
subjects affected / exposed	1 / 997 (0.10%)	0 / 1997 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Abnormal weight gain			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences (all)	0	1	
Breast milk substitute intolerance			
subjects affected / exposed	0 / 997 (0.00%)	1 / 1997 (0.05%)	
occurrences (all)	0	1	
Dairy intolerance			
subjects affected / exposed	3 / 997 (0.30%)	4 / 1997 (0.20%)	
occurrences (all)	3	4	
Decreased appetite			
subjects affected / exposed	1 / 997 (0.10%)	2 / 1997 (0.10%)	
occurrences (all)	1	2	
Dehydration			

subjects affected / exposed occurrences (all)	5 / 997 (0.50%) 5	2 / 1997 (0.10%) 2
Failure to thrive subjects affected / exposed occurrences (all)	3 / 997 (0.30%) 3	6 / 1997 (0.30%) 6
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Hypoglycaemia subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Iron deficiency subjects affected / exposed occurrences (all)	1 / 997 (0.10%) 1	1 / 1997 (0.05%) 1
Lactose intolerance subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	4 / 1997 (0.20%) 4
Malnutrition subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	5 / 1997 (0.25%) 5
Poor feeding infant subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Underweight subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	2 / 1997 (0.10%) 2
Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 997 (0.00%) 0	1 / 1997 (0.05%) 1
Weight gain poor subjects affected / exposed occurrences (all)	5 / 997 (0.50%) 5	7 / 1997 (0.35%) 7

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 February 2021	The MELODY study was amended to mitigate for the greatly reduced circulation of RSV due to measures associated with the pandemic and the challenges of operating a trial during the pandemic. In agreement with the FDA at a Type B meeting (02 December 2020) discussing the impact of COVID-19 on the registrational studies/clinical package for the BLA, the MELODY Primary Analysis would be conducted based on the 1490 subjects randomised prior to the pause in enrolment with completion of the full sample size in a complementary Safety Cohort

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
02 July 2020	study enrolment was paused due to the impact of the COVID-19 pandemic.	09 April 2021

Notes:

Limitations and caveats

None reported