Clinical trial results:
A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (GSK209762) (Priorix) compared to Merck & Co., Inc.’s MMR vaccine (M-M-R II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.

Summary

EudraCT number	2011-004891-12
Trial protocol	EE FI ES
Global end of trial date	16 April 2015

Results information

Result version number	v2 (current)
This version publication date	16 June 2018
First version publication date	30 July 2016
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	115648

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01702428
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l’Institut, 89, Rixensart, Belgium, 1330
Public contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, (44)2089 904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, (44)2089 904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 February 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To demonstrate the consistency of three manufacturing lots of INV_MMR vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.
2. To demonstrate the consistency of three manufacturing lots of INV_MMR vaccine in terms of geometric mean concentrations (GMCs) for antibodies to measles, mumps and rubella viruses at Day 42.
3. To demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR (for the two pooled lots) vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.
4. To demonstrate non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR (for the two pooled lots) vaccine in terms of GMCs for antibodies to measles, mumps and rubella viruses at Day 42.
5. To demonstrate an acceptable immune response for INV_MMR in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

Protection of trial subjects:

All subjects were observed closely for at least 30 minutes following the administration of the vaccines with appropriate medical treatment readily available in case of a rare anaphylactic reaction.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 November 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 256
Country: Number of subjects enrolled	Estonia: 501
Country: Number of subjects enrolled	Finland: 1350
Country: Number of subjects enrolled	Mexico: 394
Country: Number of subjects enrolled	United States: 2515
Worldwide total number of subjects	5016
EEA total number of subjects	2107

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	5016
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:

13 subjects from 5016 were allocated subject number but no study vaccine was administered. Therefore, the number of subjects started is 5003.

Pre-assignment

Screening details:

Sub-cohorts for this study were as follows: • US sub-cohort: Subjects recruited in US and received INV_MMR or COM_MMR co-administered with Varivax (VV), Havrix (HAV) and Prevnar (PCV-13) vaccines at Visit 1 (Day 0). • Non-US sub-cohort: Subjects recruited outside US and received INV_MMR or COM_MMR co-administered with VV and HAV vaccines at Day 0.

Pre-assignment period milestones

Number of subjects started	5016
Number of subjects completed	5003

Pre-assignment subject non-completion reasons

Reason: Number of subjects	No study vaccine administered: 13

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind[1]
Roles blinded	Subject, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

The study was conducted in a double-blind fashion, with regard to the lot-to-lot consistency evaluation of the three INV_MMR vaccine lots and in an observer-blind fashion for the comparison of the pooled lots of INV_MMR vaccine versus the pooled COM_MMR vaccine lots.

Arms

Are arms mutually exclusive?	Yes
Arm title	INV_MMR_L1 Group

Arm description:

Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 1 (L1) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Arm type	Experimental
Investigational medicinal product name	Priorix
Investigational medicinal product code	
Other name	GSK Biologicals' live attenuated measles, mumps and rubella vaccine (GSK209762)
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 dose of MMR vaccine which was administered subcutaneously in the triceps region of the left arm.

Investigational medicinal product name	Varivax
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Powder and solvent for solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 dose of VV vaccine which was administered subcutaneously in the triceps region of the right arm.

Investigational medicinal product name	Havrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 1 dose of HAV vaccine which was administered intramuscularly in the anterolateral region of the right thigh.

Investigational medicinal product name	Prevnar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

US subjects received 1 dose of PCV-13 vaccine which was administered intramuscularly in the anterolateral region of the left thigh.

Arm title	INV_MMR_L2 Group

Arm description:

Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 2 (L2) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Arm type	Experimental
Investigational medicinal product name	Priorix
Investigational medicinal product code	
Other name	GSK Biologicals' live attenuated measles, mumps and rubella vaccine (GSK209762)
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 dose of MMR vaccine which was administered subcutaneously in the triceps region of the left arm.

Investigational medicinal product name	Varivax
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 dose of VV vaccine which was administered subcutaneously in the triceps region of the right arm.

Investigational medicinal product name	Havrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 1 dose of HAV vaccine which was administered intramuscularly in the anterolateral region of the right thigh.

Investigational medicinal product name	Prevnar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

US subjects received 1 dose of PCV-13 vaccine which was administered intramuscularly in the anterolateral region of the left thigh.

Arm title	INV_MMR_L3 Group

Arm description:

Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 3 (L3) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Arm type	Experimental
Investigational medicinal product name	Priorix
Investigational medicinal product code	
Other name	GSK Biologicals' live attenuated measles, mumps and rubella vaccine (GSK209762)
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 dose of MMR vaccine which was administered subcutaneously in the triceps region of the left arm.

Investigational medicinal product name	Varivax
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 dose of VV vaccine which was administered subcutaneously in the triceps region of the right arm.

Investigational medicinal product name	Havrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 1 dose of HAV vaccine which was administered intramuscularly in the anterolateral region of the right thigh.

Investigational medicinal product name	Prevnar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

US subjects received 1 dose of PCV-13 vaccine which was administered intramuscularly in the anterolateral region of the left thigh.

Arm title	COM_MMR Group

Arm description:

Subjects received 1 dose of COM_MMR Lot 1 and Lot 2 co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively. Pooled analysis was conducted for this group.

Arm type	Active comparator
Investigational medicinal product name	Varivax
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 dose of VV vaccine which was administered subcutaneously in the triceps region of the right arm.

Investigational medicinal product name	Havrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 1 dose of HAV vaccine which was administered intramuscularly in the anterolateral region of the right thigh.

Investigational medicinal product name	Prevnar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

US subjects received 1 dose of PCV-13 vaccine which was administered intramuscularly in the anterolateral region of the left thigh.

Investigational medicinal product name	M-M-R II
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 dose of MMR vaccine which was administered subcutaneously in the triceps region of the left arm.

Notes:

[1] - The roles blinded appear to be inconsistent with a double blind trial.

Justification: The study was conducted in a double-blind fashion, with regard to the lot-to-lot consistency evaluation of the three INV_MMR vaccine lots and in an observer-blind fashion for the comparison of the pooled lots of INV_MMR vaccine versus COM_MMR vaccine.

Number of subjects in period 1[2]	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group
Started	1239	1232	1243
Completed	1175	1162	1190
Not completed	64	70	53
Lost Health Plan	3	5	-
Consent withdrawn by subject	21	23	14

Adverse event, non-fatal	2	-	-
Parents cannot assist to site	1	-	1
Mother transferred care	-	1	-
Lost to follow-up	33	41	37
Parents too busy	1	-	-
Protocol deviation	3	-	1
Lost Coverage	-	-	-

Number of subjects in period 1[2]	COM_MMR Group
Started	1289
Completed	1232
Not completed	57
Lost Health Plan	2
Consent withdrawn by subject	10
Adverse event, non-fatal	-
Parents cannot assist to site	-
Mother transferred care	-
Lost to follow-up	44
Parents too busy	-
Protocol deviation	-
Lost Coverage	1

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: 13 subjects from 5016 were allocated subject number but no study vaccine was administered. Therefore, the number of subjects started is 5003.

Baseline characteristics

Reporting groups	
Reporting group title	INV_MMR_L1 Group
Reporting group description:	
Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 1 (L1) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.	
Reporting group title	INV_MMR_L2 Group
Reporting group description:	
Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 2 (L2) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.	
Reporting group title	INV_MMR_L3 Group
Reporting group description:	
Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 3 (L3) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.	
Reporting group title	COM_MMR Group
Reporting group description:	
Subjects received 1 dose of COM_MMR Lot 1 and Lot 2 co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively. Pooled analysis was conducted for this group.	

Reporting group values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group
Number of subjects	1239	1232	1243
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	12.3	12.3	12.3
standard deviation	± 0.7	± 0.7	± 0.7
Gender categorical Units: Subjects			
Female	607	594	615
Male	632	638	628
Race/Ethnicity, Customized Units: Subjects			
White - Arabic / North African Heritage	5	6	2

Asian - Central/South Asian Heritage	14	6	7
Other	170	155	162
Native Hawaiian or Other Pacific Islander	3	1	5
American Indian or Alaskan Native	25	37	33
White - Caucasian / European Heritage	932	938	944
Asian - South East Asian Heritage	21	25	21
African Heritage / African American	60	52	57
Asian - Japanese Heritage	1	2	2
Asian - East Asian Heritage	8	10	10

Reporting group values	COM_MMR Group	Total	
Number of subjects	1289	5003	
Age categorical Units: Subjects			

Age continuous Units: months			
arithmetic mean	12.3		
standard deviation	± 0.7	-	
Gender categorical Units: Subjects			
Female	618	2434	
Male	671	2569	
Race/Ethnicity, Customized Units: Subjects			
White - Arabic / North African Heritage	7	20	
Asian - Central/South Asian Heritage	9	36	
Other	163	650	
Native Hawaiian or Other Pacific Islander	2	11	
American Indian or Alaskan Native	31	126	
White - Caucasian / European Heritage	970	3784	
Asian - South East Asian Heritage	26	93	
African Heritage / African American	70	239	
Asian - Japanese Heritage	1	6	
Asian - East Asian Heritage	10	38	

End points

End points reporting groups

Reporting group title	INV_MMR_L1 Group

Reporting group description:

Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 1 (L1) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Reporting group title	INV_MMR_L2 Group

Reporting group description:

Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 2 (L2) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Reporting group title	INV_MMR_L3 Group

Reporting group description:

Subjects received 1 dose of GSK's candidate combined measles, mumps and rubella (MMR) investigational vaccine (INV_MMR) Lot 3 (L3) co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Reporting group title	COM_MMR Group

Reporting group description:

Subjects received 1 dose of COM_MMR Lot 1 and Lot 2 co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively. Pooled analysis was conducted for this group.

Subject analysis set title	INV_MMR Group
Subject analysis set type	Per protocol

Subject analysis set description:

This group included subjects from INV_MMR _L1, INV_MMR _L2 and INV_MMR _L3 groups for whom pooled analysis was conducted in addition to lot-to-lot consistency.

Primary: Percentage of subjects with anti-measles virus antibody concentration equal to or above the cut-off-value

End point title	Percentage of subjects with anti-measles virus antibody concentration equal to or above the cut-off-value[1]

End point description:

Seroresponse was defined as post-vaccination anti-measles virus antibody concentration ≥200 milli International Unit/Milliliter (mIU/mL) among subjects who were seronegative (antibody concentration <150 mIU/mL) before vaccination. This outcome measure is applicable to reporting groups INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 as analysis was performed on subjects who received one of the lots of INV_MMR vaccine.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the consistency of three manufacturing lots of INV_MMR vaccine in terms of seroresponse rates. This endpoint therefore presents

the results for groups applicable for this analysis (i.e., INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 Groups).

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1083	1069	1096	
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-measles ≥ 150 mIU/mL	98.2 (97.3 to 98.9)	98.9 (98.0 to 99.4)	98.1 (97.1 to 98.8)	
Anti-measles ≥ 200 mIU/mL	98.1 (97.1 to 98.8)	98.6 (97.7 to 99.2)	97.8 (96.8 to 98.6)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Difference between groups (INV_MMR_L1 Group minus INV_MMR_L2 Group) in percentage of subjects with anti-measles antibody concentration ≥200 mIU/mL.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2152
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference in seroresponse rate
Point estimate	-0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.69
upper limit	0.58

Notes:

[2] - For each pair-wise comparison, the 2-sided 95% confidence interval (CI) on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to measles virus.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Difference between groups (INV_MMR_L2 Group minus INV_MMR_L3 Group) in percentage of subjects with anti-measles antibody concentration ≥200 mIU/mL.

Comparison groups	INV_MMR_L2 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2165
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in seroresponse rate
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.35
upper limit	1.98

Notes:

[3] - For each pair-wise comparison, the 2-sided 95% confidence interval (CI) on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to measles virus.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Difference between groups (INV_MMR_L1 Group minus INV_MMR_L3 Group) in percentage of subjects with anti-measles antibody concentration ≥200 mIU/mL.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2179
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference in seroresponse rate
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.98
upper limit	1.5

Notes:

[4] - For each pair-wise comparison, the 2-sided 95% confidence interval (CI) on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to measles virus.

Primary: Anti-measles virus antibody concentrations

End point title	Anti-measles virus antibody concentrations[5]

End point description:

Antibody concentrations were expressed as Geometric Mean Concentrations (GMCs) in mIU/mL. This outcome measure is applicable to reporting groups INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 as analysis was performed on subjects who received one of the lots of INV_MMR vaccine.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the consistency of three manufacturing lots of INV_MMR vaccine in terms of geometric mean concentrations (GMCs). This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 Groups).

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1083	1069	1096	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	2970.3 (2813.2 to 3136.2)	3023.6 (2864.5 to 3191.6)	3058.3 (2893.9 to 3232.0)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L1 Group divided by INV_MMR_L2 Group) for antibodies to measles virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2152
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.06

Notes:

[6] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67;1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L1 Group divided by INV_MMR_L3 Group) for antibodies to measles virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2179
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.05

Notes:

[7] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67;1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L2 Group divided by INV_MMR_L1 Group) for antibodies to measles virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2152
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.09

Notes:

[8] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67;1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L2 Group divided by INV_MMR_L3 Group) for antibodies to measles virus at Day 42.

Comparison groups	INV_MMR_L2 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2165
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.06

Notes:

[9] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67;1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L3 Group divided by INV_MMR_L1 Group) for antibodies to measles virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2179
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.11

Notes:

[10] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L3 Group divided by INV_MMR_L2 Group) for antibodies to measles virus at Day 42.

Comparison groups	INV_MMR_L2 Group v INV_MMR_L3 Group

Number of subjects included in analysis	2165
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.09

Notes:

[11] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to measles.

Primary: Percentage of subjects with anti-mumps virus antibody concentration equal to or above the cut-off-value

End point title	Percentage of subjects with anti-mumps virus antibody concentration equal to or above the cut-off-value[12]

End point description:

Seroresponse was defined as post-vaccination anti-mumps virus antibody concentration ≥10 ELISA Unit/Milliliter (EU/mL) among subjects who were seronegative (antibody concentrations <5 EU/mL) before vaccination. This outcome measure is applicable to reporting groups INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 as analysis was performed on subjects who received one of the lots of INV_MMR vaccine.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The results for this end point were tabulated to demonstrate the consistency of three manufacturing lots of INV_MMR vaccine in terms of seroresponse rates. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 Groups).

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1062	1047	1078	
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-mumps ≥ 5 EU/mL	99.7 (99.2 to 99.9)	99.3 (98.6 to 99.7)	99.2 (98.4 to 99.6)	
Anti-mumps ≥ 10 EU/mL	98.6 (97.7 to 99.2)	98.6 (97.6 to 99.2)	98.0 (96.9 to 98.7)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Difference between groups (INV_MMR_L1 Group minus INV_MMR_L2 Group) in percentage of subjects with anti-mumps antibody concentration ≥10 EU/mL.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2109
Analysis specification	Pre-specified
Analysis type	non-inferiority[13]
Parameter estimate	Difference in seroresponse rate
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.05
upper limit	1.09

Notes:

[13] - For each pair-wise comparison, the 2-sided 95% CI on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to mumps virus.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Difference between groups (INV_MMR_L1 Group minus INV_MMR_L3 Group) in percentage of subjects with anti-mumps antibody concentration ≥10 EU/mL.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2140
Analysis specification	Pre-specified
Analysis type	non-inferiority[14]
Parameter estimate	Difference in seroresponse rate
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	1.81

Notes:

[14] - For each pair-wise comparison, the 2-sided 95% CI on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to mumps virus.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Difference between groups (INV_MMR_L2 Group minus INV_MMR_L3 Group) in percentage of subjects with anti-mumps antibody concentration ≥10 EU/mL.

Comparison groups	INV_MMR_L2 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2125
Analysis specification	Pre-specified
Analysis type	non-inferiority[15]
Parameter estimate	Difference in seroresponse rate
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	1.79

Notes:

[15] - For each pair-wise comparison, the 2-sided 95% CI on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to mumps virus.

Primary: Anti-mumps virus antibody concentration

End point title	Anti-mumps virus antibody concentration[16]

End point description:

Antibody concentrations were expressed as GMCs in EU/mL. This outcome measure is applicable to reporting groups INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 as analysis was performed on subjects who received one of the lots of INV_MMR vaccine.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the consistency of three manufacturing lots of INV_MMR vaccine in terms of GMCs. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 Groups).

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1062	1047	1078	
Units: EU/mL				
geometric mean (confidence interval 95%)				
EU/mL	71.7 (68.3 to 75.2)	76.9 (73.2 to 80.8)	69.0 (65.5 to 72.7)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L1 Group divided by INV_MMR_L2 Group) for antibodies to mumps virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2109
Analysis specification	Pre-specified
Analysis type	non-inferiority[17]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1

Notes:

[17] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to mumps.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L1 Group divided by INV_MMR_L3 Group) for antibodies to mumps virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2140
Analysis specification	Pre-specified
Analysis type	non-inferiority[18]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.11

Notes:

[18] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to mumps.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L2 Group divided by INV_MMR_L1 Group) for antibodies to mumps virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2109
Analysis specification	Pre-specified
Analysis type	non-inferiority[19]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	1.15

Notes:

[19] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to mumps.

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L2 Group divided by INV_MMR_L3 Group) for antibodies to mumps virus at Day 42.

Comparison groups	INV_MMR_L3 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2125
Analysis specification	Pre-specified
Analysis type	non-inferiority[20]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	1.19

Notes:

[20] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to mumps.

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L3 Group divided by INV_MMR_L1 Group) for antibodies to mumps virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2140
Analysis specification	Pre-specified
Analysis type	non-inferiority[21]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.03

Notes:

[21] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to mumps.

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L3 Group divided by INV_MMR_L2 Group) for antibodies to mumps virus at Day 42.

Comparison groups	INV_MMR_L3 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2125
Analysis specification	Pre-specified
Analysis type	non-inferiority[22]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	0.96

Notes:

[22] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to mumps.

Primary: Percentage of subjects with anti-rubella virus antibody concentration equal to or above the cut-off-value

End point title	Percentage of subjects with anti-rubella virus antibody concentration equal to or above the cut-off-value[23]

End point description:

Seroresponse was defined as post-vaccination anti-rubella virus antibody concentration ≥10 International Unit/Milliliter (IU/mL) among subjects who were seronegative (antibody concentrations <4 IU/mL) before vaccination. This outcome measure is applicable to reporting groups INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 as analysis was performed on subjects who received one of the lots of INV_MMR vaccine.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the consistency of three manufacturing lots of INV_MMR vaccine in terms of seroresponse rates. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 Groups).

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1083	1067	1095	
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-rubella ≥ 4 IU/mL	99.4 (98.8 to 99.8)	99.7 (99.2 to 99.9)	99.4 (98.7 to 99.7)	
Anti-rubella ≥ 10 IU/mL	97.2 (96.1 to 98.1)	97.1 (95.9 to 98.0)	97.7 (96.6 to 98.5)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Difference between groups (INV_MMR_L1 Group minus INV_MMR_L2 Group) in percentage of subjects with anti-rubella antibody concentration ≥10 IU/mL.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L2 Group
Number of subjects included in analysis	2150
Analysis specification	Pre-specified
Analysis type	non-inferiority[24]
Parameter estimate	Difference in seroresponse rate
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	1.58

Notes:

[24] - For each pair-wise comparison, the 2-sided 95% CI on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to rubella virus.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Difference between groups (INV_MMR_L1 Group minus INV_MMR_L3 Group) in percentage of subjects with anti-rubella antibody concentration ≥10 IU/mL.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group

Number of subjects included in analysis	2178
Analysis specification	Pre-specified
Analysis type	non-inferiority[25]
Parameter estimate	Difference in seroresponse rate
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.86
upper limit	0.86

Notes:

[25] - For each pair-wise comparison, the 2-sided 95% CI on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to rubella virus.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Difference between groups (INV_MMR_L2 Group minus INV_MMR_L3 Group) in percentage of subjects with anti-rubella antibody concentration ≥10 IU/mL.

Comparison groups	INV_MMR_L2 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2162
Analysis specification	Pre-specified
Analysis type	non-inferiority[26]
Parameter estimate	Difference in seroresponse rate
Point estimate	-0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.02
upper limit	0.74

Notes:

[26] - For each pair-wise comparison, the 2-sided 95% CI on the lot difference in seroresponse rates should be within the [-5%;5%] margin for antibodies to rubella virus.

Primary: Anti-rubella virus antibody concentration

End point title	Anti-rubella virus antibody concentration[27]

End point description:

Antibody concentrations were expressed as GMCs in IU/mL. This outcome measure is applicable to reporting groups INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 as analysis was performed on subjects who received one of the lots of INV_MMR vaccine.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The results for this end point were tabulated to demonstrate the consistency of three manufacturing lots of INV_MMR vaccine in terms of GMCs. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR_L1, INV_MMR_L2 and INV_MMR_L3 Groups).

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1083	1067	1095	
Units: IU/mL				
geometric mean (confidence interval 95%)				
IU/mL	57.2 (54.4 to 60.1)	53.1 (50.5 to 55.7)	57.0 (54.3 to 59.8)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L1 Group divided by INV_MMR_L2 Group) for antibodies to rubella virus at Day 42. .

Comparison groups	INV_MMR_L2 Group v INV_MMR_L1 Group
Number of subjects included in analysis	2150
Analysis specification	Pre-specified
Analysis type	non-inferiority[28]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.15

Notes:

[28] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L1 Group divided by INV_MMR_L3 Group) for antibodies to rubella virus at Day 42.

Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2178
Analysis specification	Pre-specified
Analysis type	non-inferiority[29]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.07

Notes:

[29] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Adjusted GMC ratio (INV_MMR_L2 Group divided by INV_MMR_L1 Group) for antibodies to rubella virus at Day 42.	
Comparison groups	INV_MMR_L2 Group v INV_MMR_L1 Group
Number of subjects included in analysis	2150
Analysis specification	Pre-specified
Analysis type	non-inferiority[30]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	0.99

Notes:

[30] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Adjusted GMC ratio (INV_MMR_L2 Group divided by INV_MMR_L3 Group) for antibodies to rubella virus at Day 42.	
Comparison groups	INV_MMR_L2 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2162
Analysis specification	Pre-specified
Analysis type	non-inferiority[31]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	0.99

Notes:

[31] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 5
Statistical analysis description:	
Adjusted GMC ratio (INV_MMR_L3 Group divided by INV_MMR_L1 Group) for antibodies to rubella virus at Day 42.	
Comparison groups	INV_MMR_L1 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2178
Analysis specification	Pre-specified
Analysis type	non-inferiority[32]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.07

Notes:

[32] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to measles.

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Adjusted GMC ratio (INV_MMR_L3 Group divided by INV_MMR_L2 Group) for antibodies to rubella virus at Day 42.

Comparison groups	INV_MMR_L2 Group v INV_MMR_L3 Group
Number of subjects included in analysis	2162
Analysis specification	Pre-specified
Analysis type	non-inferiority[33]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.15

Notes:

[33] - For each pair-wise comparison, the 2-sided 95% CI on the lot ratio should be within the [0.67; 1.5] margin for antibodies to measles.

Primary: Percentage of subjects with anti-measles virus antibody concentration equal to or above the cut-off-value in pooled MMR groups

End point title	Percentage of subjects with anti-measles virus antibody concentration equal to or above the cut-off-value in pooled MMR groups[34]

End point description:

Seroresponse was defined as post-vaccination anti-measles virus antibody concentration ≥200 mIU/mL among subjects who were seronegative (antibody concentration <150 mIU/mL) before vaccination. Criteria to demonstrate an acceptable immune response for INV_MMR in terms of seroresponse rates to measles virus at Day 42: The LL of 2-sided 95% CI for the seroresponse rate for the pooled INV_MMR lots is ≥90% for antibodies to measles virus.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of seroresponse rates. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1137	3248		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-measles ≥ 150 mIU/mL	98.1 (97.1 to 98.8)	98.4 (97.9 to 98.8)		
Anti-measles ≥ 200 mIU/mL	98.0 (97.0 to 98.7)	98.2 (97.6 to 98.6)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Difference in percentage (INV_MMR Group minus COM_MMR Group) of subjects with anti-measles antibody concentration at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	4385
Analysis specification	Pre-specified
Analysis type	non-inferiority[35]
Parameter estimate	Difference in seroresponse rate
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.68
upper limit	1.25

Notes:

[35] - The Lower Limit (LL) of 2-sided 95 % CI for the difference in seroresponse (INV_MMR Group minus COM_MMR Group) should be ≥-5% for antibodies to measles virus.

Primary: Anti-measles virus antibody concentrations in pooled MMR groups

End point title	Anti-measles virus antibody concentrations in pooled MMR groups[36]

End point description:

Antibody concentrations were expressed as GMCs in mIU/mL.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of GMCs. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1137	3248		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	3074.4 (2911.0 to 3246.9)	3017.4 (2923.9 to 3113.8)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for antibodies to measles virus at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	4385
Analysis specification	Pre-specified
Analysis type	non-inferiority[37]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.05

Notes:

[37] - The LL of the 2-sided 95% CI on GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.67 for antibodies to measles virus.

Primary: Percentage of subjects with anti-mumps virus antibody concentration equal to or above the cut-off-value in pooled MMR groups

End point title	Percentage of subjects with anti-mumps virus antibody concentration equal to or above the cut-off-value in pooled MMR groups[38]

End point description:

Seroresponse was defined as post-vaccination anti-mumps virus antibody concentration ≥10 EU/mL among subjects who were seronegative (antibody concentrations <5 EU/mL) before vaccination.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of seroresponse rates. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1107	3187		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-mumps ≥ 5 EU/mL	99.3 (98.6 to 99.7)	99.4 (99.1 to 99.6)		
Anti-mumps ≥ 10 EU/mL	97.6 (96.5 to 98.4)	98.4 (97.9 to 98.8)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Difference in percentage (INV_MMR Group minus COM_MMR Group) of subjects with anti-mumps antibody concentration at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	4294
Analysis specification	Pre-specified
Analysis type	non-inferiority[39]
Parameter estimate	Difference in seroresponse rate
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	1.96

Notes:

[39] - The LL of 2-sided 95 % CI for the difference in seroresponse (INV_MMR Group minus COM_MMR Group) should be ≥-5% for antibodies to mumps virus.

Primary: Anti-mumps virus antibody concentration in pooled MMR groups

End point title	Anti-mumps virus antibody concentration in pooled MMR groups[40]

End point description:

Antibody concentrations were expressed as GMCs in EU/mL.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of GMCs. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1107	3187		
Units: EU/mL				
geometric mean (confidence interval 95%)				
EU/mL	69.1 (65.7 to 72.7)	72.4 (70.4 to 74.5)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for antibodies to mumps virus at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	4294
Analysis specification	Pre-specified
Analysis type	non-inferiority[41]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.11

Notes:

[41] - The LL of the 2-sided 95% CI on GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.67 for antibodies to mumps virus.

Primary: Percentage of subjects with anti-rubella virus antibody concentration equal to or above the cut-off-value in pooled MMR groups

End point title	Percentage of subjects with anti-rubella virus antibody concentration equal to or above the cut-off-value in pooled MMR groups[42]

End point description:

Seroresponse was defined as post-vaccination anti-rubella virus antibody concentration ≥10 IU/mL among subjects who were seronegative (antibody concentrations <4 IU/mL) before vaccination. Criteria to demonstrate an acceptable immune response for INV_MMR in terms of seroresponse rates to rubella virus at Day 42: The LL of 2-sided 95% CI for the seroresponse rate for the pooled INV_MMR lots is ≥90% for antibodies to rubella virus.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of seroresponse rates. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1135	3245		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-rubella ≥ 4 IU/mL	99.6 (99.0 to 99.9)	99.5 (99.2 to 99.7)		
Anti-rubella ≥ 10 IU/mL	98.5 (97.6 to 99.1)	97.3 (96.7 to 97.9)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Difference in percentage (INV_MMR Group minus COM_MMR Group) of subjects with anti-rubella antibody concentration at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	4380
Analysis specification	Pre-specified
Analysis type	non-inferiority[43]
Parameter estimate	Difference in seroresponse rate
Point estimate	-1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	-0.15

Notes:

[43] - The LL of 2-sided 95 % CI for the difference in seroresponse (INV_MMR Group minus COM_MMR Group) should be ≥-5% for antibodies to rubella virus.

Primary: Anti-rubella virus antibody concentration in pooled MMR groups

End point title	Anti-rubella virus antibody concentration in pooled MMR

End point description:

Antibody concentrations were expressed as GMCs in IU/mL.

End point type	Primary

End point timeframe:

At Day 42

Notes:

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of GMCs. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1135	3245		
Units: IU/mL				
geometric mean (confidence interval 95%)				
IU/mL	64.0 (61.1 to 67.0)	55.7 (54.2 to 57.3)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for antibodies to rubella virus at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	4380
Analysis specification	Pre-specified
Analysis type	non-inferiority[45]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	0.92

Notes:

[45] - The LL of the 2-sided 95% CI on GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.67 for antibodies to measles virus.

Secondary: Percentage of subjects with an anti-Varicella Zoster Virus (VZV) antibody concentration equal to or above the cut-off value in US sub-cohort of pooled MMR groups

End point title	Percentage of subjects with an anti-Varicella Zoster Virus (VZV) antibody concentration equal to or above the cut-off value in US sub-cohort of pooled MMR groups[46]

End point description:

Seroresponse was defined as post-vaccination anti-VZV antibody concentration ≥75 mIU/mL among subjects who were seronegative (antibody concentration <25 mIU/mL) before vaccination.

End point type	Secondary

End point timeframe:

At Day 42

Notes:

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of seroresponse rates. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	540	1492		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-VZV ≥ 25 mIU/mL	99.6 (98.7 to 100)	99.7 (99.3 to 99.9)		
Anti-VZV ≥ 75 mIU/mL	90.9 (88.2 to 93.2)	92.2 (90.7 to 93.5)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

In US sub-cohort: Difference in percentage (INV_MMR Group minus COM_MMR Group) of subjects with anti-VZV antibody concentration at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	2032
Analysis specification	Pre-specified
Analysis type	non-inferiority[47]
Parameter estimate	Difference in seroresponse rate
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.31
upper limit	4.29

Notes:

[47] - The LL of 2-sided 95 % CI for the difference in seroresponse (pooled INV_MMR Group minus pooled COM_MMR Group) should be ≥-10% for antibodies to VZV.

Secondary: Anti-VZV virus antibody concentration in US sub-cohort of pooled MMR groups

End point title	Anti-VZV virus antibody concentration in US sub-cohort of pooled MMR groups[48]

End point description:

Antibody concentrations were expressed as GMCs in mIU/mL.

End point type	Secondary

End point timeframe:

At Day 42

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of GMCs. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	540	1492		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	167.2 (158.2 to 176.7)	169.6 (164.3 to 175)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for antibodies to VZV virus at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	2032
Analysis specification	Pre-specified
Analysis type	non-inferiority[49]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.08

Notes:

[49] - The LL of the 2-sided 95% CI on GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.67 for antibodies to VZV.

Secondary: Percentage of subjects with an anti-HAV antibody concentration equal to or above the cut-off value in US sub-cohort of pooled MMR groups

End point title	Percentage of subjects with an anti-HAV antibody concentration equal to or above the cut-off value in US sub-cohort of pooled MMR groups[50]

End point description:

Percentage of subjects with an Anti-HAV antibody concentration equal to or above 15 mIU/mL were reported.

End point type	Secondary

End point timeframe:

At Day 42

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results for this end point were tabulated to assess the immunogenicity of HAV vaccine with respect to the seroresponse rates for antibodies to HAV in the pooled INV_MMR group in contrast to the COM_MMR vaccine groups. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	285	783		
Units: Percentage of subjects				
number (confidence interval 95%)				
Percentage of subjects	87.4 (82.9 to 91.0)	88.9 (86.5 to 91.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HAV antibody concentrations in US sub-cohort of pooled MMR groups

End point title	Anti-HAV antibody concentrations in US sub-cohort of pooled MMR groups[51]

End point description:

Antibody concentrations were expressed as GMCs in mIU/mL.

End point type	Secondary

End point timeframe:

At Day 42

Notes:

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of GMCs. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	285	783		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	42.4 (38.1 to 47.2)	42.0 (39.3 to 44.8)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for antibodies to HAV virus at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group

Number of subjects included in analysis	1068
Analysis specification	Pre-specified
Analysis type	non-inferiority[52]
Method	ANOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.11

Notes:

[52] - The LL of the 2-sided 95% CI on GMC ratio (INV_MMR Group over COM_MMR Group) was ≥0.5 for antibodies to HAV virus.

Secondary: Anti-S.pneumoniae antibody concentration in US sub-cohort of pooled MMR groups

End point title	Anti-S.pneumoniae antibody concentration in US sub-cohort of pooled MMR groups[53]

End point description:

Antibody concentrations were expressed as GMCs in microgram/Milliliter (µg/mL).

End point type	Secondary

End point timeframe:

At Day 42

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The results for this end point were tabulated to demonstrate the non-inferiority of INV_MMR (for the three pooled lots) compared to COM_MMR vaccine in terms of GMCs. This endpoint therefore presents the results for groups applicable for this analysis (i.e., INV_MMR and COM_MMR Groups).

End point values	COM_MMR Group	INV_MMR Group		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	266	759		
Units: µg/mL				
geometric mean (confidence interval 95%)				
anti-PnPS 1 antibody (N = 266; 759)	2.425 (2.195 to 2.679)	2.257 (2.121 to 2.402)		
anti-PnPS 3 antibody (N = 265; 758)	0.496 (0.454 to 0.542)	0.506 (0.481 to 0.533)		
anti-PnPS 4 antibody (N = 266; 753)	1.872 (1.676 to 2.091)	1.618 (1.518 to 1.725)		
anti-PnPS 5 antibody (N = 266; 757)	2.280 (2.085 to 2.493)	2.106 (1.991 to 2.228)		
anti-PnPS 6A antibody (N = 266; 759)	5.743 (5.233 to 6.304)	5.840 (5.508 to 6.192)		
anti-PnPS 6B antibody (N = 266; 758)	5.838 (5.239 to 6.505)	5.872 (5.504 to 6.265)		
anti-PnPS 7F antibody (N = 266; 758)	3.814 (3.484 to 4.176)	3.691 (3.489 to 3.905)		
anti-PnPS 9V antibody (N = 266; 759)	2.282 (2.065 to 2.521)	2.318 (2.183 to 2.461)		
anti-PnPS 14 antibody (N = 266; 757)	7.053 (6.368 to 7.811)	6.578 (6.155 to 7.029)		

anti-PnPS 18C antibody (N = 265; 759)	2.217 (1.990 to 2.470)	2.102 (1.973 to 2.241)		
anti-PnPS 19A antibody (N = 265; 759)	4.821 (4.372 to 5.317)	4.731 (4.461 to 5.017)		
anti-PnPS 19F antibody (N = 266; 759)	4.260 (3.872 to 4.687)	4.251 (4.013 to 4.504)		
anti-PnPS 23F antibody (N = 256; 742)	2.291 (2.025 to 2.592)	2.198 (2.051 to 2.355)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 1 antibody at Day 42.	
Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[54]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.05

Notes:

[54] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 3 antibody at Day 42.	
Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[55]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.08

Notes:

[55] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 4 antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[56]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	0.98

Notes:

[56] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 5 antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[57]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.01

Notes:

[57] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 6A antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[58]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.11

Notes:

[58] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 6B antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[59]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.09

Notes:

[59] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 7F antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[60]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.03

Notes:

[60] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 9V antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group

Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[61]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.08

Notes:

[61] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 14 antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[62]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.02

Notes:

[62] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 18C antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[63]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.02

Notes:

[63] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 19A antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[64]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.07

Notes:

[64] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 19F antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[65]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.06

Notes:

[65] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

In US sub-cohort: Adjusted GMC ratio (INV_MMR Group divided by COM_MMR Group) for anti-PnPS 23F antibody at Day 42.

Comparison groups	COM_MMR Group v INV_MMR Group

Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[66]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.06

Notes:

[66] - The LL of the 2-sided 95% CI for GMC ratio (INV_MMR Group over COM_MMR Group) should be ≥0.5 for antibodies to for antibodies to PS serotypes.

Secondary: Number of subjects with any solicited local adverse events (AEs)

End point title	Number of subjects with any solicited local adverse events (AEs)

End point description:

Assessed solicited local AEs were pain, redness and swelling. Any = Occurrence of the symptom regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

During the 4-days (Days 0-3) post-vaccination period

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	COM_MMR Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1186	1175	1194	1242
Units: Participants				
Any Pain	331	315	273	349
Any Redness	296	273	301	313
Any Swelling	116	99	103	133

End point values	INV_MMR Group			
Subject group type	Subject analysis set			
Number of subjects analysed	3555			
Units: Participants				
Any Pain	919			
Any Redness	870			
Any Swelling	318			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any solicited general AEs

End point title	Number of subjects with any solicited general AEs

End point description:

Assessed solicited general AEs were drowsiness, irritability and loss of appetite. Any = Occurrence of the symptom regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

During the 15-days (Days 0-14) post-vaccination period

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	COM_MMR Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1190	1176	1200	1243
Units: Participants				
Any Drowsiness	533	535	533	586
Any Irritability/fussiness	764	729	765	819
Any Loss of appetite	546	536	526	548

End point values	INV_MMR Group			
Subject group type	Subject analysis set			
Number of subjects analysed	3566			
Units: Participants				
Any Drowsiness	1601			
Any Irritability/fussiness	2258			
Any Loss of appetite	1608			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any fever

End point title	Number of subjects reporting any fever

End point description:

Any fever = Fever ≥ 38°C.

End point type	Secondary

End point timeframe:

During the 43-days (Days 0-42) post-vaccination period

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	COM_MMR Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1190	1176	1200	1243
Units: Participants				
Participants	404	422	418	412

End point values	INV_MMR Group			
Subject group type	Subject analysis set			
Number of subjects analysed	3566			
Units: Participants				
Participants	1244			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any rash

End point title	Number of subjects reporting any rash

End point description:

Assessed were any localized or generalized rash, rash with fever, varicella-like rash, measles/rubella-like rash. Any = Occurrence of the symptom regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

During the 43-days (Days 0-42) post-vaccination period

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	COM_MMR Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1190	1176	1200	1243
Units: Participants				
Any Localized or Generalized	352	331	360	378
Any with fever	106	123	118	104
Any Varicella like	87	78	85	85
Any Measles/Rubella like	71	88	76	77

End point values	INV_MMR Group			
Subject group type	Subject analysis set			
Number of subjects analysed	3566			
Units: Participants				
Any Localized or Generalized	1043			

Any with fever	347			
Any Varicella like	250			
Any Measles/Rubella like	235			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any MMR specific solicited AEs

End point title	Number of subjects reporting any MMR specific solicited AEs

End point description:

Assessed MMR specific solicited AEs were any suspected signs of meningism including febrile convulsions and parotid/salivary gland swelling. Any = Occurrence of the symptom regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

During the 43-days (Days 0-42) post-vaccination period

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	COM_MMR Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1190	1176	1200	1243
Units: Participants				
Any febrile convulsion	4	1	5	3
Any parotid/salivary gland swelling	0	0	0	0

End point values	INV_MMR Group			
Subject group type	Subject analysis set			
Number of subjects analysed	3566			
Units: Participants				
Any febrile convulsion	10			
Any parotid/salivary gland swelling	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited AEs

End point title	Number of subjects reporting any unsolicited AEs

End point description:

Unsolicited adverse event (AE) was defined as any adverse event reported in addition to those solicited during the clinical study and also any solicited symptom with onset outside the specified period of

follow-up for solicited symptoms. Any = Occurrence of the symptom regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

During the 43-days (Days 0-42) post-vaccination period

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	COM_MMR Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1239	1232	1243	1289
Units: Participants				
Participants	615	633	609	618

End point values	INV_MMR Group			
Subject group type	Subject analysis set			
Number of subjects analysed	3714			
Units: Participants				
Participants	1857			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting AEs of specific interest

End point title	Number of subjects reporting AEs of specific interest

End point description:

AEs of specific interest included new onset chronic disease (NOCD) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting emergency room (ER) visits.

End point type	Secondary

End point timeframe:

From Day 0 through the end of study (Day 180)

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	COM_MMR Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1239	1232	1243	1289
Units: Participants				
NOCDs	40	39	49	48
AEs prompting ER visits	123	116	136	134

End point values	INV_MMR Group			
Subject group type	Subject analysis set			
Number of subjects analysed	3714			
Units: Participants				
NOCDs	128			
AEs prompting ER visits	375			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any Serious adverse events (SAEs)

End point title	Number of subjects reporting any Serious adverse events (SAEs)

End point description:

SAEs assessed include medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity. Any SAE = Occurrence of SAE regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

From Day 0 through the end of study (Day 180)

End point values	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group	COM_MMR Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1239	1232	1243	1289
Units: Participants				
Participants	21	28	28	25

End point values	INV_MMR Group			
Subject group type	Subject analysis set			
Number of subjects analysed	3714			
Units: Participants				
Participants	77			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs: From Day 0 through the end of study (Day-180); Solicited local and general symptoms: During the 4-day (Day 0-3) and 15-days (Day 0-14) post-vaccination period; Unsolicited adverse events: During the 43-days (Day 0-42) post-vaccination period.

Adverse event reporting additional description:

The analysis of the solicited symptoms was based on the Total Vaccinated cohort which included only children/doses with documented safety data (i.e., symptom screen/sheet completed).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	INV_MMR_L1 Group

Reporting group description:

Subjects received 1 dose of INV_MMR_L1 vaccine co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Reporting group title	INV_MMR_L2 Group

Reporting group description:

Subjects received 1 dose of INV_MMR_L2 vaccine co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Reporting group title	INV_MMR_L3 Group

Reporting group description:

Subjects received 1 dose of INV_MMR_L3 vaccine co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively.

Reporting group title	INV_MMR Group

Reporting group description:

This group included subjects from INV_MMR _L1, INV_MMR _L2 and INV_MMR _L3 groups for whom pooled analysis was conducted in addition to lot-to-lot consistency.

Reporting group title	COM_MMR Group

Reporting group description:

Subjects received 1 dose of COM_MMR Lot 1 and Lot 2 co-administered with VV and HAV vaccines at Visit 1 (Day 0). All US subjects were also given PCV-13 vaccine. The MMR vaccine was administered subcutaneously in the triceps region of the left arm while the VV vaccine was administered subcutaneously in the triceps region of the right arm. HAV and PCV-13 vaccines were administered intramuscularly in the anterolateral region of the right and left thigh, respectively. Pooled analysis was conducted for this group.

Serious adverse events	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 1239 (1.69%)	28 / 1232 (2.27%)	28 / 1243 (2.25%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	2 / 1239 (0.16%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Finger amputation			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	2 / 1239 (0.16%)	2 / 1232 (0.16%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 1239 (0.00%)	3 / 1232 (0.24%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 1239 (0.08%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchitis			
subjects affected / exposed	3 / 1239 (0.24%)	2 / 1232 (0.16%)	3 / 1243 (0.24%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	2 / 1243 (0.16%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycoplasma infection			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	4 / 1243 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 1239 (0.16%)	1 / 1232 (0.08%)	3 / 1243 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 1239 (0.08%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			

subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pharyngitis			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	3 / 1243 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	INV_MMR Group	COM_MMR Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	77 / 3714 (2.07%)	25 / 1289 (1.94%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Head injury			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Finger amputation			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Epilepsy			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile convulsion			
subjects affected / exposed	1 / 3714 (0.03%)	5 / 1289 (0.39%)	
occurrences causally related to treatment / all	1 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	1 / 3714 (0.03%)	2 / 1289 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (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	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial hyperreactivity			
subjects affected / exposed	3 / 3714 (0.08%)	3 / 1289 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 3714 (0.00%)	2 / 1289 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	8 / 3714 (0.22%)	2 / 1289 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Croup infectious			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastroenteritis			
subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences causally related to treatment / all	1 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis adenovirus			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpangina			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycoplasma infection			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (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	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic infection			

subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	6 / 3714 (0.16%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			

subjects affected / exposed	4 / 3714 (0.11%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	3 / 3714 (0.08%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus infection			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (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	2 / 3714 (0.05%)	3 / 1289 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral pharyngitis			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	5 / 3714 (0.13%)	3 / 1289 (0.23%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	INV_MMR_L1 Group	INV_MMR_L2 Group	INV_MMR_L3 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1089 / 1239 (87.89%)	1053 / 1232 (85.47%)	1090 / 1243 (87.69%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			

subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Pallor			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Crying			
subjects affected / exposed	4 / 1239 (0.32%)	5 / 1232 (0.41%)	2 / 1243 (0.16%)
occurrences (all)	4	7	2
Cyst			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	2	0	0
Discomfort			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Injection site bruising			
subjects affected / exposed	4 / 1239 (0.32%)	5 / 1232 (0.41%)	1 / 1243 (0.08%)
occurrences (all)	4	5	1
Injection site erosion			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Injection site erythema			

subjects affected / exposed	321 / 1239 (25.91%)	294 / 1232 (23.86%)	328 / 1243 (26.39%)
occurrences (all)	331	303	334
Injection site haematoma			
subjects affected / exposed	5 / 1239 (0.40%)	1 / 1232 (0.08%)	3 / 1243 (0.24%)
occurrences (all)	6	1	3
Injection site haemorrhage			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Injection site induration			
subjects affected / exposed	3 / 1239 (0.24%)	3 / 1232 (0.24%)	2 / 1243 (0.16%)
occurrences (all)	3	3	2
Injection site mass			
subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	0	2	1
Injection site nodule			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	335 / 1239 (27.04%)	316 / 1232 (25.65%)	275 / 1243 (22.12%)
occurrences (all)	336	317	277
Injection site papule			
subjects affected / exposed	2 / 1239 (0.16%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	2	2	1
Injection site swelling			
subjects affected / exposed	127 / 1239 (10.25%)	106 / 1232 (8.60%)	113 / 1243 (9.09%)
occurrences (all)	128	107	115
Injection site vesicles			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	1

Pyrexia			
subjects affected / exposed	405 / 1239 (32.69%)	422 / 1232 (34.25%)	419 / 1243 (33.71%)
occurrences (all)	406	423	419
Secretion discharge			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Swelling			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	1	1	0
Drug hypersensitivity			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences (all)	0	0	2
Food allergy			
subjects affected / exposed	2 / 1239 (0.16%)	2 / 1232 (0.16%)	5 / 1243 (0.40%)
occurrences (all)	2	2	6
Hypersensitivity			
subjects affected / exposed	2 / 1239 (0.16%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	2	1	1
Immunisation reaction			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	2 / 1239 (0.16%)	2 / 1232 (0.16%)	0 / 1243 (0.00%)
occurrences (all)	2	2	0
Social circumstances			

Diet noncompliance			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Balanoposthitis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences (all)	1	0	2
Bilateral breast buds			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Genital labial adhesions			
subjects affected / exposed	2 / 1239 (0.16%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	2	0	0
Vaginal mucosal blistering			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences (all)	1	0	2
Bronchial hyperreactivity			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences (all)	1	0	2
Bronchospasm			
subjects affected / exposed	1 / 1239 (0.08%)	3 / 1232 (0.24%)	3 / 1243 (0.24%)
occurrences (all)	1	3	3
Catarrh			
subjects affected / exposed	2 / 1239 (0.16%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	2	1	0
Cough			
subjects affected / exposed	33 / 1239 (2.66%)	42 / 1232 (3.41%)	38 / 1243 (3.06%)
occurrences (all)	36	42	38
Dyspnoea			

subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	2 / 1243 (0.16%)
occurrences (all)	0	1	2
Epistaxis			
subjects affected / exposed	2 / 1239 (0.16%)	4 / 1232 (0.32%)	1 / 1243 (0.08%)
occurrences (all)	2	4	1
Nasal congestion			
subjects affected / exposed	10 / 1239 (0.81%)	11 / 1232 (0.89%)	5 / 1243 (0.40%)
occurrences (all)	10	12	5
Nasal discomfort			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	1	1	0
Rales			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	2 / 1239 (0.16%)	0 / 1232 (0.00%)	4 / 1243 (0.32%)
occurrences (all)	2	0	4
Respiratory distress			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	1
Rhinitis allergic			
subjects affected / exposed	3 / 1239 (0.24%)	2 / 1232 (0.16%)	3 / 1243 (0.24%)
occurrences (all)	3	2	3
Rhinorrhoea			
subjects affected / exposed	22 / 1239 (1.78%)	23 / 1232 (1.87%)	20 / 1243 (1.61%)
occurrences (all)	23	26	21
Sinus congestion			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	2
Sneezing			

subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract congestion			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	2 / 1239 (0.16%)	6 / 1232 (0.49%)	6 / 1243 (0.48%)
occurrences (all)	3	6	6
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	2 / 1239 (0.16%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	2	1	1
Irritability			
subjects affected / exposed	765 / 1239 (61.74%)	730 / 1232 (59.25%)	768 / 1243 (61.79%)
occurrences (all)	775	741	775
Middle insomnia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	3 / 1239 (0.24%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	3	0	0
Sleep terror			

subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Tearfulness			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	2	0
Terminal insomnia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Cold agglutinins positive			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Otic examination normal			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Animal bite			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences (all)	0	0	2
Arthropod bite			
subjects affected / exposed	7 / 1239 (0.56%)	7 / 1232 (0.57%)	5 / 1243 (0.40%)
occurrences (all)	7	7	5
Arthropod sting			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences (all)	0	0	3
Bite			

subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Chemical poisoning			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Concussion			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	4 / 1239 (0.32%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	4	0	1
Corneal abrasion			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Craniocerebral injury			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Ear canal injury			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Ear injury			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Eye contusion			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Face injury			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	0 / 1243 (0.00%)
occurrences (all)	0	2	0
Foreign body in gastrointestinal tract			

subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences (all)	0	0	2
Gingival injury			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	1	1	0
Head injury			
subjects affected / exposed	5 / 1239 (0.40%)	6 / 1232 (0.49%)	6 / 1243 (0.48%)
occurrences (all)	5	6	6
Heat stroke			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Laceration			
subjects affected / exposed	5 / 1239 (0.40%)	0 / 1232 (0.00%)	2 / 1243 (0.16%)
occurrences (all)	5	0	2
Limb injury			
subjects affected / exposed	3 / 1239 (0.24%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	3	1	0
Lip injury			
subjects affected / exposed	2 / 1239 (0.16%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	2	1	0
Nail avulsion			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Radial head dislocation			
subjects affected / exposed	2 / 1239 (0.16%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	2	0	0
Road traffic accident			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Scratch			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			

subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	0	2	1
Superficial injury of eye			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 1239 (0.00%)	3 / 1232 (0.24%)	1 / 1243 (0.08%)
occurrences (all)	0	3	1
Tibia fracture			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Tongue injury			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	1	1	0
Upper limb fracture			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	1 / 1239 (0.08%)	3 / 1232 (0.24%)	1 / 1243 (0.08%)
occurrences (all)	1	3	1
Nervous system disorders			
Drooling			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Exaggerated startle response			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Febrile convulsion			
subjects affected / exposed	4 / 1239 (0.32%)	1 / 1232 (0.08%)	5 / 1243 (0.40%)
occurrences (all)	4	1	5
Gross motor delay			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	4 / 1239 (0.32%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	4	0	1

Lethargy			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Nystagmus			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Poor quality sleep			
subjects affected / exposed	4 / 1239 (0.32%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	5	0	1
Post-traumatic headache			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	534 / 1239 (43.10%)	535 / 1232 (43.43%)	533 / 1243 (42.88%)
occurrences (all)	534	535	533
Speech disorder developmental			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	4 / 1243 (0.32%)
occurrences (all)	0	2	4
Iron deficiency anaemia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Lymphadenitis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			

subjects affected / exposed	5 / 1239 (0.40%)	5 / 1232 (0.41%)	2 / 1243 (0.16%)
occurrences (all)	5	5	2
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Deafness			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Ear pain			
subjects affected / exposed	3 / 1239 (0.24%)	3 / 1232 (0.24%)	4 / 1243 (0.32%)
occurrences (all)	3	3	4
Ear swelling			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Eustachian tube dysfunction			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Otorrhoea			
subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	0 / 1243 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Dacryostenosis acquired			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	1	1	1
Eye discharge			
subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	0	2	1
Eye inflammation			

subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Eye swelling			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Eyelid oedema			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	2	0	0
Hypermetropia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Lid sulcus deepened			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Strabismus			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Anal fissure			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0

Aphthous ulcer			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Chapped lips			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	5 / 1239 (0.40%)	2 / 1232 (0.16%)	9 / 1243 (0.72%)
occurrences (all)	5	2	9
Diarrhoea			
subjects affected / exposed	64 / 1239 (5.17%)	58 / 1232 (4.71%)	49 / 1243 (3.94%)
occurrences (all)	71	63	55
Dyspepsia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Faeces soft			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Flatulence			
subjects affected / exposed	2 / 1239 (0.16%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	2	2	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 1239 (0.08%)	3 / 1232 (0.24%)	0 / 1243 (0.00%)
occurrences (all)	1	3	0
Gingival hypertrophy			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	1
Gingival swelling			
subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	0 / 1243 (0.00%)
occurrences (all)	0	2	0

Haematochezia			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Lip swelling			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	1	1	1
Oral contusion			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Oral mucosal eruption			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Post-tussive vomiting			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Ranula			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Regurgitation			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Salivary gland enlargement			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Salivary gland pain			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1

Stomatitis			
subjects affected / exposed	0 / 1239 (0.00%)	4 / 1232 (0.32%)	1 / 1243 (0.08%)
occurrences (all)	0	4	1
Teething			
subjects affected / exposed	91 / 1239 (7.34%)	92 / 1232 (7.47%)	77 / 1243 (6.19%)
occurrences (all)	114	106	92
Toothache			
subjects affected / exposed	4 / 1239 (0.32%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	6	0	1
Vomiting			
subjects affected / exposed	38 / 1239 (3.07%)	35 / 1232 (2.84%)	34 / 1243 (2.74%)
occurrences (all)	39	38	38
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Blister			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	2
Dermatitis			
subjects affected / exposed	1 / 1239 (0.08%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	1	2	1
Dermatitis allergic			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	2 / 1239 (0.16%)	3 / 1232 (0.24%)	4 / 1243 (0.32%)
occurrences (all)	2	3	4
Dermatitis contact			
subjects affected / exposed	1 / 1239 (0.08%)	2 / 1232 (0.16%)	2 / 1243 (0.16%)
occurrences (all)	1	2	2
Dermatitis diaper			
subjects affected / exposed	3 / 1239 (0.24%)	4 / 1232 (0.32%)	3 / 1243 (0.24%)
occurrences (all)	4	4	4
Drug eruption			

subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	2 / 1243 (0.16%)
occurrences (all)	0	2	2
Eczema nummular			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	2 / 1239 (0.16%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	2	1	1
Hyperhidrosis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Keratosis pilaris			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Macule			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Papule			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Prurigo			

subjects affected / exposed	2 / 1239 (0.16%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	352 / 1239 (28.41%)	331 / 1232 (26.87%)	360 / 1243 (28.96%)
occurrences (all)	352	331	360
Seborrhoea			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Skin irritation			
subjects affected / exposed	2 / 1239 (0.16%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	2	0	0
Skin mass			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Skin warm			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	1	1	1
Solar dermatitis			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Urticaria			
subjects affected / exposed	2 / 1239 (0.16%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	4	1	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Polyuria			

subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Urinary tract disorder			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Elbow deformity			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Knee deformity			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Synovial cyst			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Acute sinusitis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	1
Adenovirus infection			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	1	1	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Body tinea			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Bronchiolitis			

subjects affected / exposed	2 / 1239 (0.16%)	7 / 1232 (0.57%)	7 / 1243 (0.56%)
occurrences (all)	2	7	7
Bronchitis			
subjects affected / exposed	10 / 1239 (0.81%)	12 / 1232 (0.97%)	10 / 1243 (0.80%)
occurrences (all)	10	13	11
Bullous impetigo			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	1 / 1239 (0.08%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	1	3	1
Candida nappy rash			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	2 / 1239 (0.16%)	0 / 1232 (0.00%)	3 / 1243 (0.24%)
occurrences (all)	2	0	3
Clostridium difficile infection			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	26 / 1239 (2.10%)	21 / 1232 (1.70%)	39 / 1243 (3.14%)
occurrences (all)	26	21	41
Conjunctivitis bacterial			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Coxsackie viral infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	4 / 1239 (0.32%)	11 / 1232 (0.89%)	8 / 1243 (0.64%)
occurrences (all)	4	11	8
Ear infection			
subjects affected / exposed	9 / 1239 (0.73%)	14 / 1232 (1.14%)	4 / 1243 (0.32%)
occurrences (all)	9	14	4
Enterovirus infection			

subjects affected / exposed	1 / 1239 (0.08%)	2 / 1232 (0.16%)	0 / 1243 (0.00%)
occurrences (all)	1	2	0
Epstein-barr virus infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Exanthema subitum			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	1 / 1239 (0.08%)	3 / 1232 (0.24%)	1 / 1243 (0.08%)
occurrences (all)	1	3	1
Folliculitis			
subjects affected / exposed	0 / 1239 (0.00%)	3 / 1232 (0.24%)	1 / 1243 (0.08%)
occurrences (all)	0	3	1
Fungal infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	27 / 1239 (2.18%)	21 / 1232 (1.70%)	35 / 1243 (2.82%)
occurrences (all)	28	21	38
Gastroenteritis norovirus			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	3 / 1239 (0.24%)	6 / 1232 (0.49%)	6 / 1243 (0.48%)
occurrences (all)	3	6	6
Gastrointestinal infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	1	1	1
Hand-foot-and-mouth disease			

subjects affected / exposed	2 / 1239 (0.16%)	3 / 1232 (0.24%)	9 / 1243 (0.72%)
occurrences (all)	2	3	9
Herpangina			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Herpes simplex			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	1	1	0
Impetigo			
subjects affected / exposed	4 / 1239 (0.32%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	4	1	1
Infected bite			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	2 / 1239 (0.16%)	5 / 1232 (0.41%)	1 / 1243 (0.08%)
occurrences (all)	2	5	1
Injection site abscess			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	1 / 1239 (0.08%)	7 / 1232 (0.57%)	2 / 1243 (0.16%)
occurrences (all)	1	9	2
Lice infestation			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Localised infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	1
Molluscum contagiosum			

subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	1	1	1
Nasopharyngitis			
subjects affected / exposed	74 / 1239 (5.97%)	75 / 1232 (6.09%)	74 / 1243 (5.95%)
occurrences (all)	83	82	82
Oral candidiasis			
subjects affected / exposed	2 / 1239 (0.16%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	2	2	1
Oral herpes			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	0	1	1
Oral infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	80 / 1239 (6.46%)	75 / 1232 (6.09%)	62 / 1243 (4.99%)
occurrences (all)	86	79	67
Otitis media acute			
subjects affected / exposed	8 / 1239 (0.65%)	7 / 1232 (0.57%)	13 / 1243 (1.05%)
occurrences (all)	10	7	14
Otitis media chronic			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Periorbital cellulitis			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	20 / 1239 (1.61%)	30 / 1232 (2.44%)	14 / 1243 (1.13%)
occurrences (all)	20	30	14
Pharyngitis streptococcal			

subjects affected / exposed	0 / 1239 (0.00%)	3 / 1232 (0.24%)	1 / 1243 (0.08%)
occurrences (all)	0	3	1
Pharyngotonsillitis			
subjects affected / exposed	2 / 1239 (0.16%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	2	1	1
Pneumonia			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	5 / 1243 (0.40%)
occurrences (all)	1	1	5
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	8 / 1239 (0.65%)	11 / 1232 (0.89%)	9 / 1243 (0.72%)
occurrences (all)	8	12	11
Respiratory tract infection viral			
subjects affected / exposed	3 / 1239 (0.24%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	3	1	0
Rhinitis			
subjects affected / exposed	46 / 1239 (3.71%)	49 / 1232 (3.98%)	38 / 1243 (3.06%)
occurrences (all)	50	55	42
Roseola			
subjects affected / exposed	1 / 1239 (0.08%)	2 / 1232 (0.16%)	1 / 1243 (0.08%)
occurrences (all)	1	2	1
Salmonellosis			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Scarlet fever			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	9 / 1239 (0.73%)	3 / 1232 (0.24%)	4 / 1243 (0.32%)
occurrences (all)	10	3	4

Skin bacterial infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1
Skin candida			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	1
Staphylococcal infection			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Streptococcal infection			
subjects affected / exposed	0 / 1239 (0.00%)	2 / 1232 (0.16%)	3 / 1243 (0.24%)
occurrences (all)	0	2	3
Subcutaneous abscess			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	21 / 1239 (1.69%)	9 / 1232 (0.73%)	9 / 1243 (0.72%)
occurrences (all)	22	10	11
Tooth abscess			
subjects affected / exposed	0 / 1239 (0.00%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	106 / 1239 (8.56%)	124 / 1232 (10.06%)	122 / 1243 (9.81%)
occurrences (all)	117	132	132
Urinary tract infection			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	1 / 1243 (0.08%)
occurrences (all)	2	1	1
Viral diarrhoea			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	1	0	1
Viral infection			
subjects affected / exposed	15 / 1239 (1.21%)	21 / 1232 (1.70%)	23 / 1243 (1.85%)
occurrences (all)	15	22	26
Viral pharyngitis			

subjects affected / exposed	2 / 1239 (0.16%)	2 / 1232 (0.16%)	0 / 1243 (0.00%)
occurrences (all)	2	2	0
Viral rash			
subjects affected / exposed	1 / 1239 (0.08%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	1	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 1239 (0.24%)	3 / 1232 (0.24%)	4 / 1243 (0.32%)
occurrences (all)	3	3	4
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	547 / 1239 (44.15%)	537 / 1232 (43.59%)	526 / 1243 (42.32%)
occurrences (all)	548	538	528
Dehydration			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	0 / 1243 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	1 / 1239 (0.08%)	1 / 1232 (0.08%)	0 / 1243 (0.00%)
occurrences (all)	1	1	0
Polydipsia			
subjects affected / exposed	0 / 1239 (0.00%)	0 / 1232 (0.00%)	1 / 1243 (0.08%)
occurrences (all)	0	0	1

Non-serious adverse events	INV_MMR Group	COM_MMR Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3232 / 3714 (87.02%)	1138 / 1289 (88.29%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	

Pallor			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Crying			
subjects affected / exposed	11 / 3714 (0.30%)	4 / 1289 (0.31%)	
occurrences (all)	13	5	
Cyst			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Discomfort			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Feeling hot			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Influenza like illness			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Injection site bruising			
subjects affected / exposed	10 / 3714 (0.27%)	2 / 1289 (0.16%)	
occurrences (all)	10	2	
Injection site erosion			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Injection site erythema			
subjects affected / exposed	943 / 3714 (25.39%)	335 / 1289 (25.99%)	
occurrences (all)	968	341	
Injection site haematoma			
subjects affected / exposed	9 / 3714 (0.24%)	0 / 1289 (0.00%)	
occurrences (all)	10	0	

Injection site haemorrhage			
subjects affected / exposed	2 / 3714 (0.05%)	2 / 1289 (0.16%)	
occurrences (all)	2	2	
Injection site induration			
subjects affected / exposed	8 / 3714 (0.22%)	3 / 1289 (0.23%)	
occurrences (all)	8	3	
Injection site mass			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Injection site nodule			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Injection site pain			
subjects affected / exposed	926 / 3714 (24.93%)	352 / 1289 (27.31%)	
occurrences (all)	930	352	
Injection site papule			
subjects affected / exposed	5 / 3714 (0.13%)	5 / 1289 (0.39%)	
occurrences (all)	5	5	
Injection site swelling			
subjects affected / exposed	346 / 3714 (9.32%)	139 / 1289 (10.78%)	
occurrences (all)	350	142	
Injection site vesicles			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Oedema peripheral			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Pain			
subjects affected / exposed	2 / 3714 (0.05%)	2 / 1289 (0.16%)	
occurrences (all)	2	2	
Pyrexia			
subjects affected / exposed	1246 / 3714 (33.55%)	412 / 1289 (31.96%)	
occurrences (all)	1248	412	
Secretion discharge			

subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Swelling			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Vessel puncture site haematoma			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Drug hypersensitivity			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Food allergy			
subjects affected / exposed	9 / 3714 (0.24%)	4 / 1289 (0.31%)	
occurrences (all)	10	4	
Hypersensitivity			
subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences (all)	4	2	
Immunisation reaction			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Milk allergy			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Seasonal allergy			
subjects affected / exposed	4 / 3714 (0.11%)	1 / 1289 (0.08%)	
occurrences (all)	4	1	
Social circumstances			
Diet noncompliance			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Reproductive system and breast disorders			

Acquired phimosis			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Balanoposthitis			
subjects affected / exposed	3 / 3714 (0.08%)	1 / 1289 (0.08%)	
occurrences (all)	3	1	
Bilateral breast buds			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Genital labial adhesions			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Vaginal mucosal blistering			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	3 / 3714 (0.08%)	4 / 1289 (0.31%)	
occurrences (all)	3	5	
Bronchial hyperreactivity			
subjects affected / exposed	3 / 3714 (0.08%)	2 / 1289 (0.16%)	
occurrences (all)	3	2	
Bronchospasm			
subjects affected / exposed	7 / 3714 (0.19%)	2 / 1289 (0.16%)	
occurrences (all)	7	2	
Catarrh			
subjects affected / exposed	3 / 3714 (0.08%)	2 / 1289 (0.16%)	
occurrences (all)	3	2	
Cough			
subjects affected / exposed	113 / 3714 (3.04%)	36 / 1289 (2.79%)	
occurrences (all)	116	38	
Dyspnoea			
subjects affected / exposed	3 / 3714 (0.08%)	2 / 1289 (0.16%)	
occurrences (all)	3	2	
Epistaxis			

subjects affected / exposed	7 / 3714 (0.19%)	2 / 1289 (0.16%)	
occurrences (all)	7	2	
Nasal congestion			
subjects affected / exposed	26 / 3714 (0.70%)	11 / 1289 (0.85%)	
occurrences (all)	27	11	
Nasal discomfort			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Rales			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Respiratory disorder			
subjects affected / exposed	6 / 3714 (0.16%)	1 / 1289 (0.08%)	
occurrences (all)	6	1	
Respiratory distress			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Respiratory tract congestion			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Rhinitis allergic			
subjects affected / exposed	8 / 3714 (0.22%)	1 / 1289 (0.08%)	
occurrences (all)	8	1	
Rhinorrhoea			
subjects affected / exposed	65 / 3714 (1.75%)	21 / 1289 (1.63%)	
occurrences (all)	70	22	
Sinus congestion			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Sneezing			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Tonsillar hypertrophy			

subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract congestion			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Wheezing			
subjects affected / exposed	14 / 3714 (0.38%)	1 / 1289 (0.08%)	
occurrences (all)	15	1	
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Depressed mood			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	4 / 3714 (0.11%)	1 / 1289 (0.08%)	
occurrences (all)	4	1	
Irritability			
subjects affected / exposed	2263 / 3714 (60.93%)	822 / 1289 (63.77%)	
occurrences (all)	2291	838	
Middle insomnia			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Restlessness			
subjects affected / exposed	1 / 3714 (0.03%)	2 / 1289 (0.16%)	
occurrences (all)	1	2	
Sleep disorder			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Sleep terror			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Tearfulness			

subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Terminal insomnia			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Investigations			
Cardiac murmur			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Cold agglutinins positive			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Otic examination normal			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Weight decreased			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Animal bite			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Arthropod bite			
subjects affected / exposed	19 / 3714 (0.51%)	4 / 1289 (0.31%)	
occurrences (all)	19	4	
Arthropod sting			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Bite			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Chemical poisoning			

subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Clavicle fracture			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Concussion			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Contusion			
subjects affected / exposed	5 / 3714 (0.13%)	4 / 1289 (0.31%)	
occurrences (all)	5	4	
Corneal abrasion			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Craniocerebral injury			
subjects affected / exposed	1 / 3714 (0.03%)	2 / 1289 (0.16%)	
occurrences (all)	1	2	
Ear canal injury			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Ear injury			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Eye contusion			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Face injury			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Fall			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Foreign body in gastrointestinal tract			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Gingival injury			

subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Hand fracture			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Head injury			
subjects affected / exposed	17 / 3714 (0.46%)	2 / 1289 (0.16%)	
occurrences (all)	17	2	
Heat stroke			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Laceration			
subjects affected / exposed	7 / 3714 (0.19%)	2 / 1289 (0.16%)	
occurrences (all)	7	2	
Limb injury			
subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences (all)	4	2	
Lip injury			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Nail avulsion			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Radial head dislocation			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Road traffic accident			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Scratch			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Skin abrasion			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Superficial injury of eye			

subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Thermal burn			
subjects affected / exposed	4 / 3714 (0.11%)	1 / 1289 (0.08%)	
occurrences (all)	4	1	
Tibia fracture			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Tongue injury			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Upper limb fracture			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Wound			
subjects affected / exposed	5 / 3714 (0.13%)	1 / 1289 (0.08%)	
occurrences (all)	5	1	
Nervous system disorders			
Drooling			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Exaggerated startle response			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Febrile convulsion			
subjects affected / exposed	10 / 3714 (0.27%)	3 / 1289 (0.23%)	
occurrences (all)	10	3	
Gross motor delay			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	5 / 3714 (0.13%)	1 / 1289 (0.08%)	
occurrences (all)	5	1	
Lethargy			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	

Nystagmus			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Poor quality sleep			
subjects affected / exposed	5 / 3714 (0.13%)	1 / 1289 (0.08%)	
occurrences (all)	6	1	
Post-traumatic headache			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Somnolence			
subjects affected / exposed	1602 / 3714 (43.13%)	586 / 1289 (45.46%)	
occurrences (all)	1602	586	
Speech disorder developmental			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Tremor			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 3714 (0.16%)	0 / 1289 (0.00%)	
occurrences (all)	6	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Leukopenia			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Lymphadenitis			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Lymphadenopathy			
subjects affected / exposed	12 / 3714 (0.32%)	4 / 1289 (0.31%)	
occurrences (all)	12	4	
Ear and labyrinth disorders			

Cerumen impaction			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Deafness			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Ear pain			
subjects affected / exposed	10 / 3714 (0.27%)	4 / 1289 (0.31%)	
occurrences (all)	10	4	
Ear swelling			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Eustachian tube dysfunction			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Excessive cerumen production			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Otorrhoea			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Dacryostenosis acquired			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Eye discharge			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Eye inflammation			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Eye irritation			

subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Eye swelling			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Eyelid oedema			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Hypermetropia			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Lacrimation increased			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Lid sulcus deepened			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Strabismus			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Abdominal pain			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Abdominal pain upper			
subjects affected / exposed	1 / 3714 (0.03%)	4 / 1289 (0.31%)	
occurrences (all)	1	6	
Anal fissure			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Aphthous ulcer			
subjects affected / exposed	0 / 3714 (0.00%)	2 / 1289 (0.16%)	
occurrences (all)	0	2	

Chapped lips			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	16 / 3714 (0.43%)	8 / 1289 (0.62%)	
occurrences (all)	16	8	
Diarrhoea			
subjects affected / exposed	171 / 3714 (4.60%)	64 / 1289 (4.97%)	
occurrences (all)	189	68	
Dyspepsia			
subjects affected / exposed	0 / 3714 (0.00%)	2 / 1289 (0.16%)	
occurrences (all)	0	2	
Dysphagia			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Faeces soft			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Flatulence			
subjects affected / exposed	5 / 3714 (0.13%)	1 / 1289 (0.08%)	
occurrences (all)	5	1	
Gastrooesophageal reflux disease			
subjects affected / exposed	4 / 3714 (0.11%)	3 / 1289 (0.23%)	
occurrences (all)	4	3	
Gingival hypertrophy			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Gingival pain			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Gingival swelling			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Haematochezia			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	

Lip swelling			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	3 / 3714 (0.08%)	1 / 1289 (0.08%)	
occurrences (all)	3	1	
Oral contusion			
subjects affected / exposed	0 / 3714 (0.00%)	2 / 1289 (0.16%)	
occurrences (all)	0	2	
Oral mucosal eruption			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Post-tussive vomiting			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Ranula			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Rectal haemorrhage			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Regurgitation			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	2	
Salivary gland enlargement			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Salivary gland pain			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Salivary hypersecretion			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	2	
Stomatitis			
subjects affected / exposed	5 / 3714 (0.13%)	1 / 1289 (0.08%)	
occurrences (all)	5	1	

Teething			
subjects affected / exposed	260 / 3714 (7.00%)	95 / 1289 (7.37%)	
occurrences (all)	312	114	
Toothache			
subjects affected / exposed	5 / 3714 (0.13%)	6 / 1289 (0.47%)	
occurrences (all)	7	7	
Vomiting			
subjects affected / exposed	107 / 3714 (2.88%)	43 / 1289 (3.34%)	
occurrences (all)	115	46	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Blister			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Dermatitis			
subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences (all)	4	2	
Dermatitis allergic			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Dermatitis atopic			
subjects affected / exposed	9 / 3714 (0.24%)	3 / 1289 (0.23%)	
occurrences (all)	9	3	
Dermatitis contact			
subjects affected / exposed	5 / 3714 (0.13%)	0 / 1289 (0.00%)	
occurrences (all)	5	0	
Dermatitis diaper			
subjects affected / exposed	10 / 3714 (0.27%)	5 / 1289 (0.39%)	
occurrences (all)	12	5	
Drug eruption			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Dry skin			

subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Eczema			
subjects affected / exposed	4 / 3714 (0.11%)	5 / 1289 (0.39%)	
occurrences (all)	4	5	
Eczema nummular			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Erythema			
subjects affected / exposed	4 / 3714 (0.11%)	1 / 1289 (0.08%)	
occurrences (all)	4	1	
Hyperhidrosis			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Hyperkeratosis			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Ingrowing nail			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Keratosis pilaris			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Macule			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Miliaria			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Papule			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Prurigo			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Pruritus			

subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	1043 / 3714 (28.08%)	378 / 1289 (29.33%)	
occurrences (all)	1043	378	
Seborrhoea			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Skin irritation			
subjects affected / exposed	2 / 3714 (0.05%)	2 / 1289 (0.16%)	
occurrences (all)	2	2	
Skin mass			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Skin warm			
subjects affected / exposed	3 / 3714 (0.08%)	1 / 1289 (0.08%)	
occurrences (all)	3	1	
Solar dermatitis			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Swelling face			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Urticaria			
subjects affected / exposed	4 / 3714 (0.11%)	0 / 1289 (0.00%)	
occurrences (all)	6	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Polyuria			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Urinary tract disorder			

subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Elbow deformity			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Knee deformity			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Synovial cyst			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Abscess limb			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Acute sinusitis			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Adenovirus infection			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Body tinea			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Bronchiolitis			
subjects affected / exposed	16 / 3714 (0.43%)	6 / 1289 (0.47%)	
occurrences (all)	16	6	
Bronchitis			

subjects affected / exposed	32 / 3714 (0.86%)	12 / 1289 (0.93%)	
occurrences (all)	34	13	
Bullous impetigo			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Candida infection			
subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences (all)	5	2	
Candida nappy rash			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Cellulitis			
subjects affected / exposed	5 / 3714 (0.13%)	0 / 1289 (0.00%)	
occurrences (all)	5	0	
Clostridium difficile infection			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis			
subjects affected / exposed	86 / 3714 (2.32%)	32 / 1289 (2.48%)	
occurrences (all)	88	33	
Conjunctivitis bacterial			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Coxsackie viral infection			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Croup infectious			
subjects affected / exposed	23 / 3714 (0.62%)	6 / 1289 (0.47%)	
occurrences (all)	23	6	
Ear infection			
subjects affected / exposed	27 / 3714 (0.73%)	13 / 1289 (1.01%)	
occurrences (all)	27	13	
Enterovirus infection			
subjects affected / exposed	3 / 3714 (0.08%)	2 / 1289 (0.16%)	
occurrences (all)	3	2	
Epstein-barr virus infection			

subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Exanthema subitum			
subjects affected / exposed	0 / 3714 (0.00%)	2 / 1289 (0.16%)	
occurrences (all)	0	2	
Eye infection			
subjects affected / exposed	5 / 3714 (0.13%)	4 / 1289 (0.31%)	
occurrences (all)	5	4	
Folliculitis			
subjects affected / exposed	4 / 3714 (0.11%)	0 / 1289 (0.00%)	
occurrences (all)	4	0	
Fungal infection			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Gastroenteritis			
subjects affected / exposed	83 / 3714 (2.23%)	31 / 1289 (2.40%)	
occurrences (all)	87	32	
Gastroenteritis norovirus			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis viral			
subjects affected / exposed	15 / 3714 (0.40%)	6 / 1289 (0.47%)	
occurrences (all)	15	6	
Gastrointestinal infection			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Gingivitis			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Hand-foot-and-mouth disease			
subjects affected / exposed	14 / 3714 (0.38%)	5 / 1289 (0.39%)	
occurrences (all)	14	5	
Herpangina			

subjects affected / exposed	2 / 3714 (0.05%)	2 / 1289 (0.16%)	
occurrences (all)	2	2	
Herpes simplex			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Hordeolum			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Impetigo			
subjects affected / exposed	6 / 3714 (0.16%)	2 / 1289 (0.16%)	
occurrences (all)	6	2	
Infected bite			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Influenza			
subjects affected / exposed	8 / 3714 (0.22%)	10 / 1289 (0.78%)	
occurrences (all)	8	12	
Injection site abscess			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Laryngitis			
subjects affected / exposed	10 / 3714 (0.27%)	6 / 1289 (0.47%)	
occurrences (all)	12	6	
Lice infestation			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Localised infection			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Lower respiratory tract infection			
subjects affected / exposed	2 / 3714 (0.05%)	2 / 1289 (0.16%)	
occurrences (all)	2	2	
Molluscum contagiosum			
subjects affected / exposed	3 / 3714 (0.08%)	0 / 1289 (0.00%)	
occurrences (all)	3	0	
Nasopharyngitis			

subjects affected / exposed	223 / 3714 (6.00%)	65 / 1289 (5.04%)	
occurrences (all)	247	68	
Oral candidiasis			
subjects affected / exposed	5 / 3714 (0.13%)	0 / 1289 (0.00%)	
occurrences (all)	5	0	
Oral herpes			
subjects affected / exposed	2 / 3714 (0.05%)	2 / 1289 (0.16%)	
occurrences (all)	2	2	
Oral infection			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Otitis externa			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Otitis media			
subjects affected / exposed	217 / 3714 (5.84%)	86 / 1289 (6.67%)	
occurrences (all)	232	89	
Otitis media acute			
subjects affected / exposed	28 / 3714 (0.75%)	9 / 1289 (0.70%)	
occurrences (all)	31	9	
Otitis media chronic			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Paronychia			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Periorbital cellulitis			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	
Pharyngitis			
subjects affected / exposed	64 / 3714 (1.72%)	23 / 1289 (1.78%)	
occurrences (all)	64	24	
Pharyngitis streptococcal			
subjects affected / exposed	4 / 3714 (0.11%)	0 / 1289 (0.00%)	
occurrences (all)	4	0	
Pharyngotonsillitis			

subjects affected / exposed	4 / 3714 (0.11%)	2 / 1289 (0.16%)	
occurrences (all)	4	2	
Pneumonia			
subjects affected / exposed	7 / 3714 (0.19%)	1 / 1289 (0.08%)	
occurrences (all)	7	1	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Respiratory tract infection			
subjects affected / exposed	28 / 3714 (0.75%)	7 / 1289 (0.54%)	
occurrences (all)	31	9	
Respiratory tract infection viral			
subjects affected / exposed	4 / 3714 (0.11%)	4 / 1289 (0.31%)	
occurrences (all)	4	4	
Rhinitis			
subjects affected / exposed	133 / 3714 (3.58%)	41 / 1289 (3.18%)	
occurrences (all)	147	44	
Roseola			
subjects affected / exposed	4 / 3714 (0.11%)	0 / 1289 (0.00%)	
occurrences (all)	4	0	
Salmonellosis			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Scarlet fever			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Sinusitis			
subjects affected / exposed	16 / 3714 (0.43%)	3 / 1289 (0.23%)	
occurrences (all)	17	3	
Skin bacterial infection			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	

Skin candida			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Staphylococcal infection			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Streptococcal infection			
subjects affected / exposed	5 / 3714 (0.13%)	3 / 1289 (0.23%)	
occurrences (all)	5	3	
Subcutaneous abscess			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Tonsillitis			
subjects affected / exposed	39 / 3714 (1.05%)	15 / 1289 (1.16%)	
occurrences (all)	43	16	
Tooth abscess			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	352 / 3714 (9.48%)	122 / 1289 (9.46%)	
occurrences (all)	381	129	
Urinary tract infection			
subjects affected / exposed	3 / 3714 (0.08%)	2 / 1289 (0.16%)	
occurrences (all)	4	2	
Viral diarrhoea			
subjects affected / exposed	2 / 3714 (0.05%)	1 / 1289 (0.08%)	
occurrences (all)	2	1	
Viral infection			
subjects affected / exposed	59 / 3714 (1.59%)	15 / 1289 (1.16%)	
occurrences (all)	63	15	
Viral pharyngitis			
subjects affected / exposed	4 / 3714 (0.11%)	1 / 1289 (0.08%)	
occurrences (all)	4	1	
Viral rash			
subjects affected / exposed	1 / 3714 (0.03%)	1 / 1289 (0.08%)	
occurrences (all)	1	1	

Viral tonsillitis			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Viral upper respiratory tract infection			
subjects affected / exposed	10 / 3714 (0.27%)	3 / 1289 (0.23%)	
occurrences (all)	10	3	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1610 / 3714 (43.35%)	549 / 1289 (42.59%)	
occurrences (all)	1614	550	
Dehydration			
subjects affected / exposed	0 / 3714 (0.00%)	1 / 1289 (0.08%)	
occurrences (all)	0	1	
Lactose intolerance			
subjects affected / exposed	2 / 3714 (0.05%)	0 / 1289 (0.00%)	
occurrences (all)	2	0	
Polydipsia			
subjects affected / exposed	1 / 3714 (0.03%)	0 / 1289 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported