Clinical trial results:
A Phase 1/2a, Randomized, Double-blind, Placebo-controlled, Dose-escalation Study to Evaluate the Safety, Tolerability, Immunogenicity and Vaccine-like Viral Shedding of MEDI-534, a Live, Attenuated Intranasal Vaccine Against Respiratory Syncytial Virus (RSV) and Parainfluenza Virus Type 3 (PIV3), in Healthy 6 to < 24 Month-old Children and in 2 Month-old Infants

Summary

EudraCT number	2008-002651-24
Trial protocol	DE GB FI ES BE
Global end of trial date	23 August 2012

Results information

Result version number	v1
This version publication date	02 May 2016
First version publication date	06 August 2015

Trial information

Trial identification

Sponsor protocol code	MI-CP178

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00686075
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedImmune, LLC.
Sponsor organisation address	One MedImmune Way, Gaithersburg, MD, United States, 20878
Public contact	Filip Dubovsky, Vice President, Clinical Development, MedImmune, LLC., dubovskyf@medimmune.com
Scientific contact	Filip Dubovsky, Vice President, Clinical Development, MedImmune, LLC., dubovskyf@medimmune.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 August 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 August 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to describe the safety and tolerability of multiple doses of MEDI-534 at 105 or 106 TCID50 in RSV and PIV3 seronegative subjects 6 to < 24 months of age and at dosages of 104, 105, or 106 TCID50 in unscreened infants 2 months of age.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the International Conference on Harmonization guideline E6: Good Clinical Practice. Participating participant signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 July 2008
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 390
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Brazil: 23
Country: Number of subjects enrolled	Finland: 17
Country: Number of subjects enrolled	Spain: 142
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	Australia: 13
Country: Number of subjects enrolled	Israel: 18
Country: Number of subjects enrolled	South Africa: 110
Worldwide total number of subjects	720
EEA total number of subjects	163

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	720
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 720 participants were randomized in the study. An additional 618 participants were screened but not randomized in the study.

Pre-assignment

Screening details:

A total of 720 participants were randomized in the study. An additional 618 participants were screened but not randomized in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	MEDI-534, Cohort 1

Arm description:

Participants aged 6 to less than (<) 24 months received MEDI-534, 10^5 median tissue culture infectious dose (TCID50) by intranasal route at Month 0, 2, and 4.

Arm type	Experimental
Investigational medicinal product name	MEDI-534
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 6 to less than (<) 24 months will receive MEDI-534, 10^5 median tissue culture infectious dose (TCID50) by intranasal route at Month 0, 2, and 4.

Arm title	Placebo, Cohort 1

Arm description:

Participants aged 6 to <24 months received placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 6 to <24 months will receive placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Arm title	MEDI-534, Cohort 2

Arm description:

Participants aged 6 to <24 months received MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Experimental

Investigational medicinal product name	MEDI-534
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

PParticipants aged 6 to <24 months will receive MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Arm title	Placebo, Cohort 2

Arm description:

Participants aged 6 to <24 months received placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 6 to <24 months will receive placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Arm title	MEDI-534, Cohort 3

Arm description:

Participants aged 2 months received MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Experimental
Investigational medicinal product name	MEDI-534
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 2 months will receive MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.

Arm title	Placebo, Cohort 3

Arm description:

Participants aged 2 months received placebo matched to MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 2 months will receive placebo matched to MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.

Arm title	MEDI-534, Cohort 4

Arm description:

Participants aged 2 months received MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Experimental

Investigational medicinal product name	MEDI-535
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 2 months will receive MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Arm title	Placebo, Cohort 4

Arm description:

Participants aged 2 months received placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 2 months will receive placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Arm title	MEDI-534, Cohort 5

Arm description:

Participants aged 2 months received MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Experimental
Investigational medicinal product name	MEDI-534
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 2 months will receive MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4

Arm title	Placebo, Cohort 5

Arm description:

Participants aged 2 months received placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nasal drops, solution
Routes of administration	Nasal use

Dosage and administration details:

Participants aged 2 months will receive placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Number of subjects in period 1	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2
Started	79	81	80
Treated	78	79	80
Completed	71	71	74
Not completed	8	10	6
Consent withdrawn by subject	4	3	3
Lost to follow-up	3	6	3
unspecified	1	1	-

Number of subjects in period 1	Placebo, Cohort 2	MEDI-534, Cohort 3	Placebo, Cohort 3
Started	80	40	40
Treated	80	40	40
Completed	71	36	37
Not completed	9	4	3
Consent withdrawn by subject	7	1	-
Lost to follow-up	2	3	3
unspecified	-	-	-

Number of subjects in period 1	MEDI-534, Cohort 4	Placebo, Cohort 4	MEDI-534, Cohort 5
Started	82	78	81
Treated	82	77	80
Completed	82	76	75
Not completed	0	2	6
Consent withdrawn by subject	-	2	4
Lost to follow-up	-	-	2
unspecified	-	-	-

Number of subjects in period 1	Placebo, Cohort 5
Started	79
Treated	78
Completed	69
Not completed	10
Consent withdrawn by subject	6
Lost to follow-up	3
unspecified	1

Baseline characteristics

Reporting groups	
Reporting group title	MEDI-534, Cohort 1
Reporting group description:	
Participants aged 6 to less than (<) 24 months received MEDI-534, 10^5 median tissue culture infectious dose (TCID50) by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 1
Reporting group description:	
Participants aged 6 to <24 months received placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	MEDI-534, Cohort 2
Reporting group description:	
Participants aged 6 to <24 months received MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 2
Reporting group description:	
Participants aged 6 to <24 months received placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	MEDI-534, Cohort 3
Reporting group description:	
Participants aged 2 months received MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 3
Reporting group description:	
Participants aged 2 months received placebo matched to MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	MEDI-534, Cohort 4
Reporting group description:	
Participants aged 2 months received MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 4
Reporting group description:	
Participants aged 2 months received placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	MEDI-534, Cohort 5
Reporting group description:	
Participants aged 2 months received MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 5
Reporting group description:	
Participants aged 2 months received placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.	

Reporting group values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2
Number of subjects	79	81	80
Age categorical Units: Subjects			
6 to 24 Months	79	81	80
2 Months	0	0	0
Age continuous Units: months			
arithmetic mean	9.91	9.36	11.39
standard deviation	± 3.7	± 4.04	± 4.89

Gender, Male/Female Units: participants			
Female	40	36	35
Male	39	45	45
Age, Customized Units: Subjects			
Less than (<) 6 months	0	0	0
6 to <24 months	79	81	80

Reporting group values	Placebo, Cohort 2	MEDI-534, Cohort 3	Placebo, Cohort 3
Number of subjects	80	40	40
Age categorical Units: Subjects			
6 to 24 Months	80	0	0
2 Months	0	40	40
Age continuous Units: months			
arithmetic mean	3.51	1.48	1.53
standard deviation	± 9.5	± 0.51	± 0.51
Gender, Male/Female Units: participants			
Female	40	21	18
Male	40	19	22
Age, Customized Units: Subjects			
Less than (<) 6 months	0	40	40
6 to <24 months	80	0	0

Reporting group values	MEDI-534, Cohort 4	Placebo, Cohort 4	MEDI-534, Cohort 5
Number of subjects	82	78	81
Age categorical Units: Subjects			
6 to 24 Months	0	0	0
2 Months	82	78	81
Age continuous Units: months			
arithmetic mean	1.41	1.45	1.52
standard deviation	± 0.52	± 0.5	± 0.5
Gender, Male/Female Units: participants			
Female	47	41	39
Male	35	37	42
Age, Customized Units: Subjects			
Less than (<) 6 months	82	78	81
6 to <24 months	0	0	0

Reporting group values	Placebo, Cohort 5	Total	
Number of subjects	79	720	

Age categorical Units: Subjects			
6 to 24 Months	0	320	
2 Months	79	400	
Age continuous Units: months			
arithmetic mean	1.49		
standard deviation	± 0.5	-	
Gender, Male/Female Units: participants			
Female	43	360	
Male	36	360	
Age, Customized Units: Subjects			
Less than (<) 6 months	79	400	
6 to <24 months	0	320	

End points

End points reporting groups

Reporting group title	MEDI-534, Cohort 1
Reporting group description:	
Participants aged 6 to less than (<) 24 months received MEDI-534, 10^5 median tissue culture infectious dose (TCID50) by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 1
Reporting group description:	
Participants aged 6 to <24 months received placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	MEDI-534, Cohort 2
Reporting group description:	
Participants aged 6 to <24 months received MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 2
Reporting group description:	
Participants aged 6 to <24 months received placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	MEDI-534, Cohort 3
Reporting group description:	
Participants aged 2 months received MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 3
Reporting group description:	
Participants aged 2 months received placebo matched to MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	MEDI-534, Cohort 4
Reporting group description:	
Participants aged 2 months received MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 4
Reporting group description:	
Participants aged 2 months received placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	MEDI-534, Cohort 5
Reporting group description:	
Participants aged 2 months received MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.	
Reporting group title	Placebo, Cohort 5
Reporting group description:	
Participants aged 2 months received placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.	

Primary: Number of Participants With Solicited Symptoms After Dose 1

End point title	Number of Participants With Solicited Symptoms After Dose 1[1]
End point description:	
Solicited symptoms were predefined symptoms or events to be specifically inquired about and assessed daily during the 28-day period after vaccine administration. The solicited symptoms included fever greater than or equal to (>=) 100.4 degrees Fahrenheit (F), runny/stuffy nose, cough, drowsiness, loss of appetite/decreased urine output, irritability/fussiness, oropharyngeal inflammation (laryngitis), and epistaxis.	
End point type	Primary
End point timeframe:	
Within 28 days after Dose 1	

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	79	80	80
Units: participants				
Any solicited symptom	65	68	61	59
Fever: 100.4 to 101.4 degrees F	13	8	10	8
Fever: 101.5 to 103.1 degrees F	9	8	6	8
Fever: 103.2 to 104.9 degrees F	3	1	1	1
Fever: greater than (>) 104.9 degrees F	0	0	0	0
Runny/stuffy nose	50	51	50	40
Cough	27	30	33	24
Drowsiness	26	29	21	21
Loss of appetite/decreased urine output	22	26	21	21
Irritability/fussiness	40	46	41	44
Oropharyngeal inflammation	9	12	7	8
Epistaxis	4	0	4	5

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	82	77
Units: participants				
Any solicited symptom	27	24	50	48
Fever: 100.4 to 101.4 degrees F	4	4	6	1
Fever: 101.5 to 103.1 degrees F	1	3	1	4
Fever: 103.2 to 104.9 degrees F	0	1	0	0
Fever: greater than (>) 104.9 degrees F	0	0	0	0
Runny/stuffy nose	19	15	30	36
Cough	11	8	19	22
Drowsiness	10	9	15	13
Loss of appetite/decreased urine output	7	7	9	6
Irritability/fussiness	16	14	29	18
Oropharyngeal inflammation	2	2	5	7
Epistaxis	1	1	2	0

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	78		
Units: participants				
Any solicited symptom	60	53		
Fever: 100.4 to 101.4 degrees F	4	3		

Fever: 101.5 to 103.1 degrees F	2	2		
Fever: 103.2 to 104.9 degrees F	0	0		
Fever: greater than (>) 104.9 degrees F	0	0		
Runny/stuffy nose	30	30		
Cough	17	19		
Drowsiness	16	22		
Loss of appetite/decreased urine output	12	12		
Irritability/fussiness	41	32		
Oropharyngeal inflammation	3	6		
Epistaxis	0	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Symptoms After Dose 2

End point title	Number of Participants With Solicited Symptoms After Dose 2[2]

End point description:

Solicited symptoms were predefined symptoms or events to be specifically inquired about and assessed daily during the 28-day period after vaccine administration. The solicited symptoms included fever >=100.4 degrees F, runny/stuffy nose, cough, drowsiness, loss of appetite/decreased urine output, irritability/fussiness, oropharyngeal inflammation (laryngitis), and epistaxis.

End point type	Primary

End point timeframe:

Within 28 days after Dose 2

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	65	66	65
Units: participants				
Any solicited symptom	50	53	53	45
Fever: 100.4 to 101.4 degrees F	16	17	10	11
Fever: 101.5 to 103.1 degrees F	13	10	9	8
Fever: 103.2 to 104.9 degrees F	2	1	3	1
Fever: >104.9 degrees F	1	0	0	0
Runny/stuffy nose	41	35	38	34
Cough	16	23	28	22
Drowsiness	20	13	15	15
Loss of appetite/decreased urine output	16	17	14	17
Irritability/fussiness	33	29	35	25
Oropharyngeal inflammation	9	5	4	3
Epistaxis	4	4	2	4

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	26	76	71
Units: participants				
Any solicited symptom	12	19	38	42
Fever: 100.4 to 101.4 degrees F	1	2	8	4
Fever: 101.5 to 103.1 degrees F	0	1	3	1
Fever: 103.2 to 104.9 degrees F	0	0	1	0
Fever: >104.9 degrees F	0	0	0	0
Runny/stuffy nose	10	15	25	30
Cough	2	7	15	21
Drowsiness	5	4	11	7
Loss of appetite/decreased urine output	3	4	9	11
Irritability/fussiness	8	6	13	14
Oropharyngeal inflammation	2	1	4	2
Epistaxis	1	0	0	1

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	70		
Units: participants				
Any solicited symptom	39	41		
Fever: 100.4 to 101.4 degrees F	1	3		
Fever: 101.5 to 103.1 degrees F	1	0		
Fever: 103.2 to 104.9 degrees F	0	0		
Fever: >104.9 degrees F	0	0		
Runny/stuffy nose	25	24		
Cough	20	20		
Drowsiness	7	10		
Loss of appetite/decreased urine output	9	9		
Irritability/fussiness	22	21		
Oropharyngeal inflammation	7	7		
Epistaxis	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Symptoms After Dose 3

End point title	Number of Participants With Solicited Symptoms After Dose 3[3]

End point description:

Solicited symptoms were predefined symptoms or events to be specifically inquired about and assessed daily during the 28-day period after vaccine administration. The solicited symptoms included fever >=100.4 degrees F, runny/stuffy nose, cough, drowsiness, loss of appetite/decreased urine output, irritability/fussiness, oropharyngeal inflammation (laryngitis), and epistaxis.

End point type	Primary

End point timeframe:

Within 28 days after Dose 3

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	63	61
Units: participants				
Any solicited symptom	41	45	48	45
Fever: 100.4 to 101.4 degrees F	8	9	9	9
Fever: 101.5 to 103.1 degrees F	6	8	6	9
Fever: 103.2 to 104.9 degrees F	0	2	2	1
Fever: >104.9 degrees F	0	0	0	0
Runny/stuffy nose	36	35	35	28
Cough	22	14	20	17
Drowsiness	12	9	11	9
Loss of appetite/decreased urine output	13	15	8	11
Irritability/fussiness	23	25	29	28
Oropharyngeal inflammation	9	4	4	2
Epistaxis	2	1	2	4

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	30	76	70
Units: participants				
Any solicited symptom	20	17	36	33
Fever: 100.4 to 101.4 degrees F	3	6	7	8
Fever: 101.5 to 103.1 degrees F	1	0	2	1
Fever: 103.2 to 104.9 degrees F	0	0	0	0
Fever: >104.9 degrees F	0	0	0	0
Runny/stuffy nose	16	15	24	21
Cough	10	10	14	15
Drowsiness	2	6	4	4
Loss of appetite/decreased urine output	8	4	8	10
Irritability/fussiness	11	8	11	11
Oropharyngeal inflammation	1	3	2	4
Epistaxis	0	2	0	0

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	68		
Units: participants				

Any solicited symptom	48	41		
Fever: 100.4 to 101.4 degrees F	10	10		
Fever: 101.5 to 103.1 degrees F	4	4		
Fever: 103.2 to 104.9 degrees F	1	0		
Fever: >104.9 degrees F	0	0		
Runny/stuffy nose	32	31		
Cough	25	23		
Drowsiness	7	9		
Loss of appetite/decreased urine output	11	11		
Irritability/fussiness	20	14		
Oropharyngeal inflammation	8	6		
Epistaxis	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) After Dose 1

End point title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs) After Dose 1[4]

End point description:

An adverse event (AE) was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Treatment-emergent adverse events (TEAEs) for Dose 1 are events between administration of Dose 1 and up to 28 days after the dose that were absent before treatment or that worsened relative to pretreatment state. Number of participants with unsolicited TEAEs (spontaneously reported events) after Dose 1 were reported.

End point type	Primary

End point timeframe:

Within 28 days after Dose 1

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	79	80	80
Units: participants	51	51	47	35

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	82	77
Units: participants	15	15	20	26

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	78		
Units: participants	29	21		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) After Dose 2

End point title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs) After Dose 2[5]

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Treatment-Emergent Adverse Events (TEAEs) for Dose 2 are events between administration of Dose 2 and up to 28 days after the dose that were absent before treatment or that worsened relative to pretreatment state. Number of participants with unsolicited TEAEs (spontaneously reported events) after Dose 2 were reported.

End point type	Primary

End point timeframe:

Within 28 days after Dose 2

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	65	66	65
Units: participants	31	41	31	27

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	26	76	71
Units: participants	9	10	21	21

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	70		
Units: participants	25	24		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) After Dose 3

End point title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs) After Dose 3[6]

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Treatment-Emergent Adverse Events (TEAEs) for Dose 3 are events between administration of Dose 3 and up to 28 days after the dose that were absent before treatment or that worsened relative to pretreatment state. Number of participants with unsolicited TEAEs (spontaneously reported events) after Dose 3 were reported.

End point type	Primary

End point timeframe:

Within 28 days after Dose 3

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	63	61
Units: participants	34	35	33	25

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	30	76	70
Units: participants	11	10	25	22

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	68		
Units: participants	29	27		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-Emergent Serious Adverse Events (TESAEs) After Dose 1

End point title	Number of Participants With Treatment-Emergent Serious Adverse Events (TESAEs) After Dose 1[7]

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. A serious adverse event (SAE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-Emergent Serious Adverse Events (TESAEs) are serious events between administration of Dose 1 and up to 28 days after the dose that were absent before treatment or that worsened relative to pretreatment state. Number of participants with unsolicited TESAEs (spontaneously reported events) after Dose 1 were reported.

End point type	Primary

End point timeframe:

Within 28 days after Dose 1

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	79	80	80
Units: participants	0	0	0	0

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	82	77
Units: participants	0	0	0	0

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	78		
Units: participants	2	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-Emergent Serious Adverse Events

(TESAEs) After Dose 2

End point title	Number of Participants With Treatment-Emergent Serious Adverse Events (TESAEs) After Dose 2[8]

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-Emergent Serious Adverse Events (TESAEs) are serious events between administration of Dose 2 and up to 28 days after the dose that were absent before treatment or that worsened relative to pretreatment state. Number of participants with unsolicited TESAEs (spontaneously reported events) after Dose 2 were reported.

End point type	Primary

End point timeframe:

Within 28 days after Dose 2

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	65	66	65
Units: participants	1	0	0	0

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	26	76	71
Units: participants	0	1	0	1

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	70		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-Emergent Serious Adverse Events (TESAEs) After Dose 3

End point title	Number of Participants With Treatment-Emergent Serious Adverse Events (TESAEs) After Dose 3[9]

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to

possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-Emergent Serious Adverse Events (TESAEs) are serious events between administration of Dose 3 and up to 28 days after the dose that were absent before treatment or that worsened relative to pretreatment state. Number of participants with unsolicited TESAEs (spontaneously reported events) after Dose 3 were reported.

End point type	Primary

End point timeframe:

Within 28 days after Dose 3

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	63	61
Units: participants	0	1	0	0

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	30	76	70
Units: participants	1	0	0	0

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	68		
Units: participants	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Medically-Attended Lower Respiratory Illnesses (MA-LRIs) After Dose 1

End point title	Number of Participants With Medically-Attended Lower Respiratory Illnesses (MA-LRIs) After Dose 1[10]

End point description:

An MA-LRI was a healthcare provider-confirmed diagnosis of one or more of the following events: wheezing, pneumonia, croup (laryngotracheobronchitis), rhonchi (not cleared with cough or suctioning), rales (not cleared with cough or suctioning), bronchitis, bronchiolitis, and apnea.

End point type	Primary

End point timeframe:

Within 28 days after Dose 1

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	79	80	80
Units: participants	2	2	4	4

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	82	77
Units: participants	0	0	1	0

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	78		
Units: participants	0	2		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Medically-Attended Lower Respiratory Illnesses (MA-LRIs) After Dose 2

End point title	Number of Participants With Medically-Attended Lower Respiratory Illnesses (MA-LRIs) After Dose 2[11]

End point description:

An MA-LRI was a healthcare provider-confirmed diagnosis of one or more of the following events: wheezing, pneumonia, croup (laryngotracheobronchitis), rhonchi (not cleared with cough or suctioning), rales (not cleared with cough or suctioning), bronchitis, bronchiolitis, and apnea.

End point type	Primary

End point timeframe:

Within 28 days after Dose 2

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	65	66	65
Units: participants	3	3	1	3

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	26	76	71
Units: participants	1	2	0	2

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	70		
Units: participants	3	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Medically-Attended Lower Respiratory Illnesses (MA-LRIs) After Dose 3

End point title	Number of Participants With Medically-Attended Lower Respiratory Illnesses (MA-LRIs) After Dose 3[12]

End point description:

An MA-LRI was a healthcare provider-confirmed diagnosis of one or more of the following events: wheezing, pneumonia, croup (laryngotracheobronchitis), rhonchi (not cleared with cough or suctioning), rales (not cleared with cough or suctioning), bronchitis, bronchiolitis, and apnea.

End point type	Primary

End point timeframe:

Within 28 days after Dose 3

Notes:

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

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	63	61
Units: participants	3	0	7	3

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	30	76	70
Units: participants	2	2	1	1

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	68		
Units: participants	7	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who Shed Vaccine-Type Virus

End point title	Number of Participants who Shed Vaccine-Type Virus

End point description:

Nasal wash specimens were collected to assess vaccine virus recovery in the upper respiratory tract on 7, 12 and 28 days after each dosing.

End point type	Secondary

End point timeframe:

7, 12 and 28 days after Dose 1, 2 and 3

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	76	78	78	79
Units: participants				
Dose 1: Day 7 (n=76,76,78,79,40,39,82,77,78,75)	33	0	41	0
Dose 1: Day 12 (n=75,78,78,78,40,40,81,76,78,76)	21	0	14	0
Dose 1: Day 28 (n=76,77,77,78,39,40,82,76,77,76)	2	0	1	0
Dose 2: Day 7 (n=62,65,65,63,25,26,75,70,72,68)	9	0	6	0
Dose 2: Day 12 (n=63,65,65,64,25,25,76,71,72,68)	2	0	1	0
Dose 2: Day 28 (n=63,65,65,65,25,26,76,71,73,68)	0	0	0	0
Dose 3: Day 7 (n=58,59,62,59,28,30,75,70,69,68)	6	0	1	0
Dose 3: Day 12 (n=59,60,61,61,28,29,76,70,70,68)	1	0	0	0
Dose 3: Day 28 (n=60,60,63,61,28,30,76,70,71,68)	0	0	0	0

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	82	77
Units: participants				
Dose 1: Day 7 (n=76,76,78,79,40,39,82,77,78,75)	22	0	50	0
Dose 1: Day 12 (n=75,78,78,78,40,40,81,76,78,76)	16	0	29	0
Dose 1: Day 28 (n=76,77,77,78,39,40,82,76,77,76)	3	0	4	0
Dose 2: Day 7 (n=62,65,65,63,25,26,75,70,72,68)	5	0	20	0
Dose 2: Day 12 (n=63,65,65,64,25,25,76,71,72,68)	3	0	7	0
Dose 2: Day 28 (n=63,65,65,65,25,26,76,71,73,68)	0	0	0	0
Dose 3: Day 7 (n=58,59,62,59,28,30,75,70,69,68)	4	1	18	0
Dose 3: Day 12 (n=59,60,61,61,28,29,76,70,70,68)	0	0	5	0
Dose 3: Day 28 (n=60,60,63,61,28,30,76,70,71,68)	0	0	1	0

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	76		
Units: participants				
Dose 1: Day 7 (n=76,76,78,79,40,39,82,77,78,75)	52	0		
Dose 1: Day 12 (n=75,78,78,78,40,40,81,76,78,76)	22	0		
Dose 1: Day 28 (n=76,77,77,78,39,40,82,76,77,76)	5	0		
Dose 2: Day 7 (n=62,65,65,63,25,26,75,70,72,68)	13	0		
Dose 2: Day 12 (n=63,65,65,64,25,25,76,71,72,68)	4	0		
Dose 2: Day 28 (n=63,65,65,65,25,26,76,71,73,68)	0	0		
Dose 3: Day 7 (n=58,59,62,59,28,30,75,70,69,68)	11	0		
Dose 3: Day 12 (n=59,60,61,61,28,29,76,70,70,68)	4	0		
Dose 3: Day 28 (n=60,60,63,61,28,30,76,70,71,68)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Seroresponse to Respiratory Syncytial Virus (RSV) and Human Parainfluenza Virus Type 3 (hPIV3) After Dose 3

End point title	Percentage of Participants With a Seroresponse to Respiratory Syncytial Virus (RSV) and Human Parainfluenza Virus Type 3 (hPIV3) After Dose 3

End point description:

Seroresponse was defined as a >=4-fold rise from Baseline in neutralizing antibody titer, regardless of Baseline serostatus. Respiratory Syncytial Virus (RSV) and hPIV3 antibody titers were determined by using microneutralization assay and hemagglutination inhibition assay, respectively. Clopper-pearson exact confidence interval was reported.

End point type	Secondary

End point timeframe:

Day 28 after Dose 3

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	53	51	53
Units: percentage of participants				
number (confidence interval)				
RSV (n=44, 51, 50, 51, 19, 19, 68, 59, 63, 61)	29.5 (16.8 to 45.2)	17.6 (8.4 to 30.9)	36 (22.9 to 50.8)	25.5 (14.3 to 39.6)
hPIV3 (n=55, 53, 51, 53, 20, 22, 65, 59, 57, 52)	67.3 (53.3 to 79.3)	7.5 (2.1 to 18.2)	86.3 (73.7 to 94.3)	11.3 (4.3 to 23)

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	22	68	59
Units: percentage of participants				
number (confidence interval)				
RSV (n=44, 51, 50, 51, 19, 19, 68, 59, 63, 61)	15.8 (3.4 to 39.6)	5.3 (0.1 to 26)	7.4 (2.4 to 16.3)	3.4 (0.4 to 11.7)
hPIV3 (n=55, 53, 51, 53, 20, 22, 65, 59, 57, 52)	35 (15.4 to 59.2)	4.5 (0.1 to 22.8)	16.9 (8.8 to 28.3)	5.1 (1.1 to 14.1)

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	63	61		
Units: percentage of participants				
number (confidence interval)				
RSV (n=44, 51, 50, 51, 19, 19, 68, 59, 63, 61)	0 (0 to 5.7)	0 (0 to 5.9)		
hPIV3 (n=55, 53, 51, 53, 20, 22, 65, 59, 57, 52)	19.3 (10 to 31.9)	5.8 (1.2 to 15.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Genotypic Stability of Recovered Vaccine-Type Virus

End point title	Genotypic Stability of Recovered Vaccine-Type Virus

End point description:

Nasal wash samples with vaccine-type virus were evaluated for genotypic stability, defined as the presence of the entire RSV-Fusion (RSV F) insert based on the RSV F sequence results. If the insert was absent or truncated, the recovered virus was counted as genotypically unstable. Nasal wash samples were categorized as genotypically stable, genotypically unstable or undetermined genotypic stability.

End point type	Secondary

End point timeframe:

Within 28 days after any dose

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	0[13]	48	0[14]
Units: nasal wash samples				
Genotypically stable	77		67	
Genotypically unstable	0		0	
Undetermined genotypic stability	4		0	

Notes:

[13] - No participant was analyzed for this endpoint in this reporting group.

[14] - No participant was analyzed for this endpoint in this reporting group

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	1	67	0[15]
Units: nasal wash samples				
Genotypically stable	54	1	135	
Genotypically unstable	0	0	0	
Undetermined genotypic stability	5	0	6	

Notes:

[15] - No participant was analyzed for this endpoint in this reporting group

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	0[16]		
Units: nasal wash samples				
Genotypically stable	110			

Genotypically unstable	0			
Undetermined genotypic stability	7			

Notes:

[16] - No participant was analyzed for this endpoint in this reporting group

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Medically-Attended Lower Respiratory Illnesses (MA-LRIs) Through 365 Days After Randomization

End point title	Number of Participants With Medically-Attended Lower Respiratory Illnesses (MA-LRIs) Through 365 Days After Randomization

End point description:

An MA-LRI was a healthcare provider-confirmed diagnosis of one or more of the following events: wheezing, pneumonia, croup (laryngotracheobronchitis), rhonchi (not cleared with cough or suctioning), rales (not cleared with cough or suctioning), bronchitis, bronchiolitis, and apnea. MA-LRIs occurring within 28 days post any dose and after 28 days post any dose were summarized separately.

End point type	Secondary

End point timeframe:

Day 0 to Day 365

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	79	80	80
Units: participants				
Within 28 days post any dose	8	5	12	10
After 28 days post any dose	16	16	18	10

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	82	77
Units: participants				
Within 28 days post any dose	3	4	2	3
After 28 days post any dose	6	7	13	20

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	78		
Units: participants				
Within 28 days post any dose	10	7		

After 28 days post any dose	23	15		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Significant New Medical Conditions (SNMCs) Through 365 Days After Randomization

End point title	Number of Participants With Significant New Medical Conditions (SNMCs) Through 365 Days After Randomization

End point description:

An SNMC was a newly diagnosed medical condition that was of a chronic, ongoing nature and was assessed by the investigator as medically significant. Examples of SNMCs include diabetes, asthma, autoimmune disease (for example, lupus, rheumatoid arthritis), and neurological disease (for example, epilepsy, autism).

End point type	Secondary

End point timeframe:

Day 0 to Day 365

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	79	80	80
Units: participants	0	0	1	1

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	82	77
Units: participants	0	0	3	1

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	78		
Units: participants	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Serious Adverse Events (TESAEs) Through 365 Days After Randomization

End point title	Number of Participants With Treatment-Emergent Serious Adverse Events (TESAEs) Through 365 Days After Randomization

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-Emergent Serious Adverse Events (TESAEs) are serious events after administration of drug which were absent before treatment or that worsened relative to pretreatment state. Number of participants with unsolicited TESAEs (spontaneously reported events) within 365 days after randomization were reported.

End point type	Secondary

End point timeframe:

Day 0 to Day 365

End point values	MEDI-534, Cohort 1	Placebo, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	79	80	80
Units: participants	6	5	5	1

End point values	MEDI-534, Cohort 3	Placebo, Cohort 3	MEDI-534, Cohort 4	Placebo, Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	82	77
Units: participants	1	2	3	4

End point values	MEDI-534, Cohort 5	Placebo, Cohort 5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	78		
Units: participants	9	3		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 0 to Day 365

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	12.0

Reporting groups

Reporting group title	MEDI-534, Cohort 1

Reporting group description:

Participants aged 6 to less than (<) 24 months received MEDI-534, 10^5 median tissue culture infectious dose (TCID50) by intranasal route at Month 0, 2, and 4.

Reporting group title	MEDI-534, Cohort 2

Reporting group description:

Participants aged 6 to <24 months received MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Reporting group title	Placebo, Cohort 2

Reporting group description:

Participants aged 6 to <24 months received placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Reporting group title	Placebo, Cohort 1

Reporting group description:

Participants aged 6 to <24 months received placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Reporting group title	MEDI-534, Cohort 3

Reporting group description:

Participants aged 2 months received MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.

Reporting group title	Placebo, Cohort 3

Reporting group description:

Participants aged 2 months received placebo matched to MEDI-534, 10^4 TCID50 by intranasal route at Month 0, 2, and 4.

Reporting group title	MEDI-534, Cohort 4

Reporting group description:

Participants aged 2 months received MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Reporting group title	Placebo, Cohort 4

Reporting group description:

Participants aged 2 months received placebo matched to MEDI-534, 10^5 TCID50 by intranasal route at Month 0, 2, and 4.

Reporting group title	MEDI-534, Cohort 5

Reporting group description:

Participants aged 2 months received MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Reporting group title	Placebo, Cohort 5

Reporting group description:

Participants aged 2 months received placebo matched to MEDI-534, 10^6 TCID50 by intranasal route at Month 0, 2, and 4.

Serious adverse events	MEDI-534, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 78 (7.69%)	5 / 80 (6.25%)	1 / 80 (1.25%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (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
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (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
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (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
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (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
Anal abscess			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (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
Bronchiolitis			
subjects affected / exposed	1 / 78 (1.28%)	1 / 80 (1.25%)	0 / 80 (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
Cellulitis			

subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (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
Croup infectious			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (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
Gastroenteritis			
subjects affected / exposed	3 / 78 (3.85%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (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
Parainfluenzae virus infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (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
Pneumonia			
subjects affected / exposed	2 / 78 (2.56%)	0 / 80 (0.00%)	0 / 80 (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
Pyelonephritis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (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
Respiratory tract infection			

subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (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
Tonsillitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (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
Urinary tract infection			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (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 infection			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (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	Placebo, Cohort 1	MEDI-534, Cohort 3	Placebo, Cohort 3
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 79 (6.33%)	1 / 40 (2.50%)	2 / 40 (5.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Nervous system disorders			
Febrile convulsion			

subjects affected / exposed	2 / 79 (2.53%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Anal abscess			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Bronchiolitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (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 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (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

Measles			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Osteomyelitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Pneumonia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Pyelonephritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Respiratory tract infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Tonsillitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Urinary tract infection			

subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (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
Viral infection			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (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

Serious adverse events	MEDI-534, Cohort 4	Placebo, Cohort 4	MEDI-534, Cohort 5
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 82 (3.66%)	4 / 77 (5.19%)	9 / 80 (11.25%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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
Anal abscess			

subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
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	2 / 82 (2.44%)	2 / 77 (2.60%)	2 / 80 (2.50%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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
Croup infectious			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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
Gastroenteritis			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	3 / 80 (3.75%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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
Osteomyelitis			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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
Pneumonia			

subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (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
Tonsillitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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
Urinary tract infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (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
Viral infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo, Cohort 5		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 78 (3.85%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Croup infectious			

subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Measles				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal bacteraemia				

subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	MEDI-534, Cohort 1	MEDI-534, Cohort 2	Placebo, Cohort 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 78 (83.33%)	59 / 80 (73.75%)	55 / 80 (68.75%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Feeling hot			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site pain			

subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Irritability			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Multiple allergies			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 78 (1.28%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Choking			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	5 / 78 (6.41%)	1 / 80 (1.25%)	3 / 80 (3.75%)
occurrences (all)	5	1	3
Dysphonia			

subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Laryngeal stenosis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	2 / 78 (2.56%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	2	1	0
Nasal discomfort			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Nasal dryness			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Postnasal drip			
subjects affected / exposed	2 / 78 (2.56%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	3	0	0
Respiratory disorder			
subjects affected / exposed	1 / 78 (1.28%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	1	1	1
Respiratory tract congestion			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Rhinorrhoea			

subjects affected / exposed	3 / 78 (3.85%)	2 / 80 (2.50%)	0 / 80 (0.00%)
occurrences (all)	5	3	0
Rhonchi			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Sneezing			
subjects affected / exposed	0 / 78 (0.00%)	3 / 80 (3.75%)	2 / 80 (2.50%)
occurrences (all)	0	3	2
Throat irritation			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract congestion			
subjects affected / exposed	1 / 78 (1.28%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	2 / 78 (2.56%)	4 / 80 (5.00%)	3 / 80 (3.75%)
occurrences (all)	2	4	3
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	3	0	1
Sleep disorder			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Investigations			
Body temperature increased			
subjects affected / exposed	6 / 78 (7.69%)	9 / 80 (11.25%)	6 / 80 (7.50%)
occurrences (all)	9	9	7
Cardiac murmur			

subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Occult blood			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	3	0	2
Contusion			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Excoriation			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Gingival injury			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 78 (0.00%)	4 / 80 (5.00%)	0 / 80 (0.00%)
occurrences (all)	0	5	0
Joint sprain			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Scratch			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tongue injury			

subjects affected / exposed	1 / 78 (1.28%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Traumatic haematoma			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Vaccination complication			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Poor quality sleep			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Lymphadenopathy			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ear pain			

subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Middle ear effusion			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Otorrhoea			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane hyperaemia			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	6 / 78 (7.69%)	4 / 80 (5.00%)	3 / 80 (3.75%)
occurrences (all)	7	4	4
Conjunctivitis allergic			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Eye pruritus			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed	2 / 78 (2.56%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	2	0	0

Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	3	0
Constipation			
subjects affected / exposed	2 / 78 (2.56%)	2 / 80 (2.50%)	5 / 80 (6.25%)
occurrences (all)	3	3	6
Diarrhoea			
subjects affected / exposed	12 / 78 (15.38%)	17 / 80 (21.25%)	17 / 80 (21.25%)
occurrences (all)	14	23	24
Flatulence			
subjects affected / exposed	4 / 78 (5.13%)	4 / 80 (5.00%)	1 / 80 (1.25%)
occurrences (all)	4	7	2
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Infantile colic			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Intestinal haemorrhage			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Regurgitation			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Teething			
subjects affected / exposed	21 / 78 (26.92%)	22 / 80 (27.50%)	15 / 80 (18.75%)
occurrences (all)	40	44	39
Tongue geographic			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	8 / 78 (10.26%)	10 / 80 (12.50%)	11 / 80 (13.75%)
occurrences (all)	9	12	17
Vomiting projectile			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Blister			

subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dandruff			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Dermatitis diaper			
subjects affected / exposed	2 / 78 (2.56%)	5 / 80 (6.25%)	5 / 80 (6.25%)
occurrences (all)	2	6	7
Dry skin			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Eczema			
subjects affected / exposed	2 / 78 (2.56%)	3 / 80 (3.75%)	0 / 80 (0.00%)
occurrences (all)	2	3	0
Erythema			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Erythema multiforme			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Heat rash			

subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	7 / 78 (8.97%)	2 / 80 (2.50%)	5 / 80 (6.25%)
occurrences (all)	7	2	6
Rash erythematous			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Seborrhoea			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Urticaria papular			

subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Torticollis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Acute sinusitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Adenoiditis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Adenoviral conjunctivitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Adenovirus infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Body tinea			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Bronchiolitis			
subjects affected / exposed	3 / 78 (3.85%)	4 / 80 (5.00%)	6 / 80 (7.50%)
occurrences (all)	3	4	6
Bronchitis			
subjects affected / exposed	0 / 78 (0.00%)	3 / 80 (3.75%)	0 / 80 (0.00%)
occurrences (all)	0	3	0
Candida nappy rash			

subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Candidiasis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis bacterial			
subjects affected / exposed	2 / 78 (2.56%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	2	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis viral			
subjects affected / exposed	1 / 78 (1.28%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Coxsackie viral infection			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	1	0	1
Dermatitis infected			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eczema infected			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Enterovirus infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Exanthema subitum			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Fungal infection			

subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	2 / 78 (2.56%)	3 / 80 (3.75%)	2 / 80 (2.50%)
occurrences (all)	2	4	5
Gastroenteritis viral			
subjects affected / exposed	3 / 78 (3.85%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	3	0	1
Genital candidiasis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 78 (0.00%)	2 / 80 (2.50%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Herpangina			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	1	0	2
Laryngitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 78 (1.28%)	1 / 80 (1.25%)	3 / 80 (3.75%)
occurrences (all)	1	1	3
Omphalitis			

subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	11 / 78 (14.10%)	11 / 80 (13.75%)	14 / 80 (17.50%)
occurrences (all)	16	12	15
Otitis media acute			
subjects affected / exposed	7 / 78 (8.97%)	1 / 80 (1.25%)	5 / 80 (6.25%)
occurrences (all)	7	1	5
Paronychia			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Pertussis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	4 / 78 (5.13%)	4 / 80 (5.00%)	1 / 80 (1.25%)
occurrences (all)	4	4	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	2 / 80 (2.50%)
occurrences (all)	0	1	2
Pharyngotonsillitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	1	0	1
Respiratory tract infection			

subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	3 / 78 (3.85%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	3	1	1
Scarlet fever			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	4 / 78 (5.13%)	1 / 80 (1.25%)	2 / 80 (2.50%)
occurrences (all)	4	1	2
Skin candida			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	2 / 78 (2.56%)	4 / 80 (5.00%)	3 / 80 (3.75%)
occurrences (all)	2	5	5
Tonsillitis streptococcal			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	15 / 78 (19.23%)	22 / 80 (27.50%)	13 / 80 (16.25%)
occurrences (all)	19	29	14
Viral infection			
subjects affected / exposed	4 / 78 (5.13%)	4 / 80 (5.00%)	1 / 80 (1.25%)
occurrences (all)	5	4	1
Viral pharyngitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	1	0	2
Viral rash			
subjects affected / exposed	1 / 78 (1.28%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	1	1	1
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 78 (3.85%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	3	1	1
Wound infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 78 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Weight gain poor			
subjects affected / exposed	0 / 78 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Placebo, Cohort 1	MEDI-534, Cohort 3	Placebo, Cohort 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	66 / 79 (83.54%)	22 / 40 (55.00%)	27 / 40 (67.50%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Feeling hot			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			

subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Irritability			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Multiple allergies			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Seasonal allergy			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	3	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Choking			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	3 / 79 (3.80%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	5	0	0
Dysphonia			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Hiccups			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	3	0	0
Laryngeal stenosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Nasal discomfort			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Nasal dryness			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Pharyngeal erythema			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Postnasal drip			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 79 (1.27%)	3 / 40 (7.50%)	0 / 40 (0.00%)
occurrences (all)	1	5	0
Rhonchi			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	3 / 79 (3.80%)	3 / 40 (7.50%)	0 / 40 (0.00%)
occurrences (all)	4	4	0
Throat irritation			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			

subjects affected / exposed	4 / 79 (5.06%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	4	1	0
Cardiac murmur			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Occult blood			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Excoriation			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Gingival injury			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Head injury			
subjects affected / exposed	2 / 79 (2.53%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Joint sprain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Sunburn			

subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Traumatic haematoma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vaccination complication			
subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			

Cerumen impaction			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Middle ear effusion			
subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Otorrhoea			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane hyperaemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	4 / 79 (5.06%)	4 / 40 (10.00%)	1 / 40 (2.50%)
occurrences (all)	4	4	1
Conjunctivitis allergic			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Eye discharge			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Eye pruritus			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			

subjects affected / exposed	2 / 79 (2.53%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	1 / 79 (1.27%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	16 / 79 (20.25%)	4 / 40 (10.00%)	3 / 40 (7.50%)
occurrences (all)	26	4	5
Flatulence			
subjects affected / exposed	1 / 79 (1.27%)	3 / 40 (7.50%)	1 / 40 (2.50%)
occurrences (all)	1	4	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Intestinal haemorrhage			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	20 / 79 (25.32%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	53	1	1
Tongue geographic			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	13 / 79 (16.46%)	4 / 40 (10.00%)	3 / 40 (7.50%)
occurrences (all)	20	5	3
Vomiting projectile			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Jaundice			

subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dandruff			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Dermatitis allergic			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	1 / 79 (1.27%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	2	2	0
Dermatitis contact			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Dermatitis diaper			
subjects affected / exposed	9 / 79 (11.39%)	1 / 40 (2.50%)	4 / 40 (10.00%)
occurrences (all)	9	2	4
Dry skin			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	3 / 79 (3.80%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	3	0	0
Erythema			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Erythema multiforme			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	6 / 79 (7.59%)	2 / 40 (5.00%)	2 / 40 (5.00%)
occurrences (all)	6	2	2
Rash erythematous			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Seborrhoea			
subjects affected / exposed	0 / 79 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Urticaria papular			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Adenoiditis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Adenoviral conjunctivitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	3 / 79 (3.80%)	3 / 40 (7.50%)	2 / 40 (5.00%)
occurrences (all)	3	3	2
Bronchitis			

subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Candida nappy rash			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Candidiasis			
subjects affected / exposed	0 / 79 (0.00%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Cellulitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis bacterial			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis viral			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Croup infectious			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Dermatitis infected			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eczema infected			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			

subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Genital candidiasis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	2 / 79 (2.53%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	3	0	0
Influenza			
subjects affected / exposed	4 / 79 (5.06%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	4	0	0
Laryngitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			

subjects affected / exposed	2 / 79 (2.53%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	3	2	1
Omphalitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	4 / 79 (5.06%)	1 / 40 (2.50%)	2 / 40 (5.00%)
occurrences (all)	5	1	2
Oral herpes			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	11 / 79 (13.92%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	16	2	1
Otitis media acute			
subjects affected / exposed	10 / 79 (12.66%)	0 / 40 (0.00%)	2 / 40 (5.00%)
occurrences (all)	12	0	2
Paronychia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pertussis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 79 (0.00%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Pharyngitis streptococcal			
subjects affected / exposed	2 / 79 (2.53%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	2 / 79 (2.53%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Scarlet fever			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Skin candida			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	4 / 79 (5.06%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	4	0	1
Tonsillitis streptococcal			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Tracheitis			

subjects affected / exposed	0 / 79 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	26 / 79 (32.91%)	4 / 40 (10.00%)	7 / 40 (17.50%)
occurrences (all)	31	5	7
Viral infection			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	2 / 40 (5.00%)
occurrences (all)	1	0	2
Viral pharyngitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Viral rash			
subjects affected / exposed	1 / 79 (1.27%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	5 / 79 (6.33%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	5	0	0
Wound infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	0 / 79 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	MEDI-534, Cohort 4	Placebo, Cohort 4	MEDI-534, Cohort 5
Total subjects affected by non-serious adverse events			
subjects affected / exposed	45 / 82 (54.88%)	42 / 77 (54.55%)	50 / 80 (62.50%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			

Feeling hot			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Multiple allergies			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Choking			

subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	1 / 82 (1.22%)	2 / 77 (2.60%)	3 / 80 (3.75%)
occurrences (all)	1	2	3
Dysphonia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Laryngeal stenosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 82 (0.00%)	3 / 77 (3.90%)	1 / 80 (1.25%)
occurrences (all)	0	3	2
Nasal discomfort			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Pharyngeal erythema			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Postnasal drip			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			

subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	1	0	1
Rhinorrhoea			
subjects affected / exposed	2 / 82 (2.44%)	0 / 77 (0.00%)	4 / 80 (5.00%)
occurrences (all)	2	0	7
Rhonchi			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	2 / 80 (2.50%)
occurrences (all)	1	0	3
Throat irritation			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	2 / 80 (2.50%)
occurrences (all)	0	0	2
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

Investigations			
Body temperature increased			
subjects affected / exposed	1 / 82 (1.22%)	1 / 77 (1.30%)	2 / 80 (2.50%)
occurrences (all)	1	1	2
Cardiac murmur			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Occult blood			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	1 / 82 (1.22%)	2 / 77 (2.60%)	1 / 80 (1.25%)
occurrences (all)	1	2	1
Excoriation			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Gingival injury			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Sunburn			

subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Tongue injury			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Traumatic haematoma			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vaccination complication			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			

Cerumen impaction			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Middle ear effusion			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	1	0	1
Tympanic membrane hyperaemia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	4 / 82 (4.88%)	7 / 77 (9.09%)	2 / 80 (2.50%)
occurrences (all)	4	8	2
Conjunctivitis allergic			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 82 (0.00%)	2 / 77 (2.60%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Eye pruritus			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Eye swelling			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			

subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 82 (0.00%)	3 / 77 (3.90%)	1 / 80 (1.25%)
occurrences (all)	0	3	1
Abdominal pain upper			
subjects affected / exposed	1 / 82 (1.22%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	1	2	0
Constipation			
subjects affected / exposed	2 / 82 (2.44%)	5 / 77 (6.49%)	4 / 80 (5.00%)
occurrences (all)	2	5	4
Diarrhoea			
subjects affected / exposed	4 / 82 (4.88%)	2 / 77 (2.60%)	7 / 80 (8.75%)
occurrences (all)	5	2	7
Flatulence			
subjects affected / exposed	1 / 82 (1.22%)	3 / 77 (3.90%)	2 / 80 (2.50%)
occurrences (all)	1	3	2
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0

Intestinal haemorrhage			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	3 / 82 (3.66%)	7 / 77 (9.09%)	3 / 80 (3.75%)
occurrences (all)	4	8	4
Tongue geographic			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 82 (0.00%)	2 / 77 (2.60%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Umbilical hernia			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	3 / 82 (3.66%)	3 / 77 (3.90%)	6 / 80 (7.50%)
occurrences (all)	3	4	9
Vomiting projectile			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Jaundice			

subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Dandruff			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Dermatitis			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	1 / 82 (1.22%)	2 / 77 (2.60%)	0 / 80 (0.00%)
occurrences (all)	1	2	0
Dermatitis contact			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	2 / 82 (2.44%)	3 / 77 (3.90%)	6 / 80 (7.50%)
occurrences (all)	2	3	6
Dry skin			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	5 / 82 (6.10%)	6 / 77 (7.79%)	3 / 80 (3.75%)
occurrences (all)	6	8	3
Erythema			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

Erythema multiforme			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	4 / 82 (4.88%)	2 / 77 (2.60%)	5 / 80 (6.25%)
occurrences (all)	4	2	5
Rash erythematous			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Rash generalised			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	1	0	1
Seborrhoea			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 82 (1.22%)	2 / 77 (2.60%)	0 / 80 (0.00%)
occurrences (all)	1	2	0
Skin induration			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Skin irritation			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0

Urticaria			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 82 (0.00%)	2 / 77 (2.60%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Torticollis			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Adenoiditis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Adenoviral conjunctivitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	1 / 82 (1.22%)	1 / 77 (1.30%)	6 / 80 (7.50%)
occurrences (all)	1	1	7
Bronchitis			

subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Candida nappy rash			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	1 / 82 (1.22%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Cellulitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Conjunctivitis viral			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	2 / 80 (2.50%)
occurrences (all)	0	0	2
Dermatitis infected			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Eczema infected			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Exanthema subitum			

subjects affected / exposed	2 / 82 (2.44%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	2	0	0
Fungal infection			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Fungal skin infection			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Furuncle			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 82 (0.00%)	3 / 77 (3.90%)	2 / 80 (2.50%)
occurrences (all)	0	3	2
Gastroenteritis viral			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			

subjects affected / exposed	5 / 82 (6.10%)	5 / 77 (6.49%)	5 / 80 (6.25%)
occurrences (all)	6	5	8
Omphalitis			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	5 / 82 (6.10%)	4 / 77 (5.19%)	4 / 80 (5.00%)
occurrences (all)	5	4	4
Oral herpes			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	2 / 82 (2.44%)	1 / 77 (1.30%)	6 / 80 (7.50%)
occurrences (all)	2	1	6
Otitis media acute			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	1	0	1
Paronychia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pertussis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	6 / 82 (7.32%)	3 / 77 (3.90%)	1 / 80 (1.25%)
occurrences (all)	7	3	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Scarlet fever			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Tinea infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 82 (1.22%)	4 / 77 (5.19%)	0 / 80 (0.00%)
occurrences (all)	1	5	0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tracheitis			

subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	15 / 82 (18.29%)	12 / 77 (15.58%)	14 / 80 (17.50%)
occurrences (all)	18	13	18
Viral infection			
subjects affected / exposed	1 / 82 (1.22%)	1 / 77 (1.30%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Viral pharyngitis			
subjects affected / exposed	1 / 82 (1.22%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Viral rash			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 82 (0.00%)	1 / 77 (1.30%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Wound infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	0 / 82 (0.00%)	0 / 77 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo, Cohort 5		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 78 (56.41%)		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			

Feeling hot subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Influenza like illness subjects affected / exposed occurrences (all)	1 / 78 (1.28%) 1		
Injection site pain subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Irritability subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Pain subjects affected / exposed occurrences (all)	1 / 78 (1.28%) 1		
Vaccination site pain subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Vessel puncture site haemorrhage subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Multiple allergies subjects affected / exposed occurrences (all)	1 / 78 (1.28%) 1		
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Bronchial hyperreactivity subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Choking			

subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Cough				
subjects affected / exposed	3 / 78 (3.85%)			
occurrences (all)	4			
Dysphonia				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Hiccups				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Laryngeal stenosis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Nasal congestion				
subjects affected / exposed	2 / 78 (2.56%)			
occurrences (all)	2			
Nasal discomfort				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Nasal dryness				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Oropharyngeal pain				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Pharyngeal erythema				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Postnasal drip				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Respiratory disorder				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Respiratory tract congestion				

subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Rhonchi			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences (all)	1		
Sinus congestion			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Sneezing			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Upper respiratory tract congestion			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	2 / 78 (2.56%)		
occurrences (all)	2		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		

Investigations			
Body temperature increased			
subjects affected / exposed	2 / 78 (2.56%)		
occurrences (all)	3		
Cardiac murmur			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Occult blood			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Excoriation			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Gingival injury			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Head injury			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Joint sprain			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Scratch			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Sunburn			

subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Tongue injury			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Traumatic haematoma			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Vaccination complication			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Poor quality sleep			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences (all)	1		
Iron deficiency anaemia			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			

Cerumen impaction			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Middle ear effusion			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Otorrhoea			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Tympanic membrane hyperaemia			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	5 / 78 (6.41%)		
occurrences (all)	5		
Conjunctivitis allergic			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences (all)	1		
Eye discharge			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Eye pruritus			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Eye swelling			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Lacrimation increased			

subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Ocular hyperaemia			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	5 / 78 (6.41%)		
occurrences (all)	7		
Flatulence			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences (all)	1		
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 78 (2.56%)		
occurrences (all)	2		
Haematochezia			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Infantile colic			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		

Intestinal haemorrhage			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Oral pain			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Regurgitation			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Teething			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences (all)	1		
Tongue geographic			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Umbilical hernia			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	3 / 78 (3.85%)		
occurrences (all)	4		
Vomiting projectile			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Jaundice			

subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Dandruff			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Dermatitis atopic			
subjects affected / exposed	2 / 78 (2.56%)		
occurrences (all)	3		
Dermatitis contact			
subjects affected / exposed	2 / 78 (2.56%)		
occurrences (all)	2		
Dermatitis diaper			
subjects affected / exposed	2 / 78 (2.56%)		
occurrences (all)	2		
Dry skin			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	2 / 78 (2.56%)		
occurrences (all)	2		
Erythema			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		

Erythema multiforme				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Heat rash				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Hyperhidrosis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Periorbital oedema				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	2 / 78 (2.56%)			
occurrences (all)	4			
Rash erythematous				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Rash generalised				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Rash papular				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Seborrhoea				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Seborrhoeic dermatitis				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Skin induration				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Skin irritation				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			

Urticaria			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Urticaria papular			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Torticollis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Acute sinusitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Adenoiditis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Adenoviral conjunctivitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Adenovirus infection			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Body tinea			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences (all)	0		
Bronchiolitis			
subjects affected / exposed	3 / 78 (3.85%)		
occurrences (all)	3		
Bronchitis			

subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Candida nappy rash				
subjects affected / exposed	3 / 78 (3.85%)			
occurrences (all)	3			
Candidiasis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Cellulitis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Conjunctivitis bacterial				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Conjunctivitis infective				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Conjunctivitis viral				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Coxsackie viral infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Croup infectious				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Dermatitis infected				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Eczema infected				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Enterovirus infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Exanthema subitum				

subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Fungal infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Fungal skin infection				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Furuncle				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	5 / 78 (6.41%)			
occurrences (all)	5			
Gastroenteritis viral				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Genital candidiasis				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Hand-foot-and-mouth disease				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Herpangina				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Laryngitis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				

subjects affected / exposed	7 / 78 (8.97%)			
occurrences (all)	13			
Omphalitis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	2			
Oral herpes				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	2 / 78 (2.56%)			
occurrences (all)	2			
Otitis media acute				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Paronychia				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Pertussis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Pharyngitis streptococcal				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Pneumonia				

subjects affected / exposed	1 / 78 (1.28%)			
occurrences (all)	1			
Respiratory tract infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Scarlet fever				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Skin candida				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Staphylococcal infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Subcutaneous abscess				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Tinea infection				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	3 / 78 (3.85%)			
occurrences (all)	3			
Tonsillitis streptococcal				
subjects affected / exposed	0 / 78 (0.00%)			
occurrences (all)	0			
Tracheitis				

subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	14 / 78 (17.95%) 17		
Viral infection subjects affected / exposed occurrences (all)	2 / 78 (2.56%) 2		
Viral pharyngitis subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Viral rash subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 78 (1.28%) 1		
Wound infection subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		
Weight gain poor subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 April 2008	The first Amendment updated: 1) Exclusion criterion 9: revised from "Receipt of any live virus vaccine (excluding rotavirus vaccine) within 28 days prior to randomization" to "Receipt of any live virus vaccine (excluding oral polio vaccine and rotavirus vaccine) within 28 days prior to randomization, 2) Exclusion criterion 10: revised from "Receipt of any inactivated (ie, non-live) vaccine or rotavirus vaccine" to "Receipt of any inactivated (ie, non-live) vaccine, oral polio vaccine or rotavirus vaccine", 3) Exclusion criterion 20: revised to add "for respiratory illness (excludes elective mechanical ventilation during surgery)", 4) The stratification by region was changed, 5) Updated prohibited concomitant medications, 6) Methods for sample handling, collection, and testing were updated, 7) Updated criteria for interruption of study dosing, 8) Added other analyses and Updated definitions of lower respiratory tract infections criteria in Appendix B (Respiratory Distress Severity Grading Table) of protocols.
13 June 2008	The second Amendment updated: 1) Inclusion criterion 1: wording was changed from "> 6 month of age" to "≥ 6 months of age", 2) Exclusion criterion 4: reworded, 3) Clarified 28-day post-dose window for prohibited concomitant medications, 4) The Dose 2 window was expanded from 56 ± 8 days to 56 ± 14 days post Dose 1 and 5) Updated to include criterion 5.
18 February 2009	The third Amendment updated: 1)Wording "through the end of the RSV season following vaccination or 180 days after the final dose, whichever is later" was changed to "over a 1 year follow-up after receipt of first dose of study vaccine", 2) The sentence "The study will be initiated in the RSV off season." was removed (Section 9.1, Overall Study Design and Plan Description, 3) The study flow diagram was updated, 4) The interim analysis description was clarified, 5) Table for schedule of subject evaluations was modified to indicate the timing of 1-year follow-up and to describe that unscheduled illness visits and the Day 28 visit could have been conducted at home. 6) The wording "rectal preferred" was removed and wording was added to describe that axillary temperatures were preferred for daily temperature recording of solicited symptoms post dose, 7) Respiratory syncytial virus and other explanatory text was added to the description of virology testing from nasal wash specimens, 8) The following sentence was added "MA-LRIs that occur during the 28 day post-dosing period are AEs and in addition should be reported as immediately reportable events", 9) The wording was modified to describe the process for safety review process within MedImmune, 10) The protocol stopping criteria were modified, 11) Significant new medical condition was removed as a primary endpoint and moved to a secondary endpoint, 12) Serious adverse events occurring during the entire study period was added as an additional secondary endpoint.
18 May 2009	The fourth Amendment updated: 1) Notification of Sponsor of Serious Adverse Events of protocol amendment, the following sentence was added after the first sentence of the last paragraph "All Grade 4 (Potentially Life Threatening) adverse events, regardless of presumed relationship to study product, will be reported to the US FDA as IND safety reports".

03 November 2009	The fifth Amendment updated: 1) Clinical Experience with MEDI-534 of protocol amendment was updated to include the results of preliminary blinded interim analyses of safety results from MI-CP149 and to clarify that the Safety Monitoring Committee reviewed blinded, not unblinded, data, 2) Rationale for Study in protocol was updated to include the results of preliminary blinded interim analyses of safety results from MI-CP149, 3) Interim safety analyses were updated (a) to modify the timing of possible blinded interim safety analyses to after one half of the planned number of subjects in each of Cohorts 1, 2, 3, and 4 reached 28 days post Dose 1, for the purposes of cohort progression and the proof of concept study; and (b) to provide for interim unblinded analyses of virology, immunogenicity, and safety data after all subjects in a cohort reached 28 days post final dose and 4) Interim safety analyses were updated (a) to modify the timing of possible blinded interim safety analyses to after one half of the planned number of subjects in Cohorts 1, 2, 3, and 4 reached 28 days post Dose 1, for the purposes of cohort progression and the proof of concept study; b) to specify the blinded safety data parameters to be reviewed; and c) to clarify that subjects were to be randomized to receive MEDI-534 or placebo.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported