

**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: | |
| Participants aged 6 to <24 months will receive MEDI-534, 10^6 TCID ₅₀ 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 TCID ₅₀ 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 TCID ₅₀ 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 TCID ₅₀ 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 TCID ₅₀ 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 TCID ₅₀ 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 TCID ₅₀ 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 TCID ₅₀ 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 (\geq) 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

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

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 occurrences (all) | 1 / 78 (1.28%) 1 | 1 / 80 (1.25%) 1 | 0 / 80 (0.00%) 0 |
| Traumatic haematoma subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 1 / 80 (1.25%) 1 |
| Vaccination complication subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Nervous system disorders Febrile convulsion subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 1 / 80 (1.25%) 1 |
| Headache subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 1 / 80 (1.25%) 1 |
| Poor quality sleep subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 1 / 80 (1.25%) 1 | 0 / 80 (0.00%) 0 |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Iron deficiency anaemia subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Leukocytosis subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 1 / 80 (1.25%) 1 | 0 / 80 (0.00%) 0 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Ear and labyrinth disorders Cerumen impaction subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 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 occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 1 / 80 (1.25%) 1 |
| Torticollis subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Infections and infestations | | | |
| Acarodermatitis subjects affected / exposed occurrences (all) | 1 / 78 (1.28%) 1 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Acute sinusitis subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Adenoiditis subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 1 / 80 (1.25%) 1 |
| Adenoviral conjunctivitis subjects affected / exposed occurrences (all) | 1 / 78 (1.28%) 1 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Adenovirus infection subjects affected / exposed occurrences (all) | 1 / 78 (1.28%) 1 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Body tinea subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 1 / 80 (1.25%) 1 |
| Bronchiolitis subjects affected / exposed occurrences (all) | 3 / 78 (3.85%) 3 | 4 / 80 (5.00%) 4 | 6 / 80 (7.50%) 6 |
| Bronchitis subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 3 / 80 (3.75%) 3 | 0 / 80 (0.00%) 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 occurrences (all) | 15 / 78 (19.23%) 19 | 22 / 80 (27.50%) 29 | 13 / 80 (16.25%) 14 |
| Viral infection subjects affected / exposed occurrences (all) | 4 / 78 (5.13%) 5 | 4 / 80 (5.00%) 4 | 1 / 80 (1.25%) 1 |
| Viral pharyngitis subjects affected / exposed occurrences (all) | 1 / 78 (1.28%) 1 | 0 / 80 (0.00%) 0 | 2 / 80 (2.50%) 2 |
| Viral rash subjects affected / exposed occurrences (all) | 1 / 78 (1.28%) 1 | 1 / 80 (1.25%) 1 | 1 / 80 (1.25%) 1 |
| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | 3 / 78 (3.85%) 3 | 1 / 80 (1.25%) 1 | 1 / 80 (1.25%) 1 |
| Wound infection subjects affected / exposed occurrences (all) | 1 / 78 (1.28%) 1 | 0 / 80 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 0 / 80 (0.00%) 0 | 1 / 80 (1.25%) 1 |
| Weight gain poor subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | 1 / 80 (1.25%) 1 | 0 / 80 (0.00%) 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 occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| General disorders and administration site conditions Feeling hot subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 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 occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Tongue injury subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Traumatic haematoma subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Vaccination complication subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 |
| Nervous system disorders Febrile convulsion subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Poor quality sleep subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Iron deficiency anaemia subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Leukocytosis subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Ear and labyrinth disorders | | | |

| | | | |
|--|---------------------|----------------------|---------------------|
| Cerumen impaction subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Ear pain subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Middle ear effusion subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 |
| Otorrhoea subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Tympanic membrane hyperaemia subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctival haemorrhage subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Conjunctivitis subjects affected / exposed occurrences (all) | 4 / 79 (5.06%) 4 | 4 / 40 (10.00%) 4 | 1 / 40 (2.50%) 1 |
| Conjunctivitis allergic subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Eye discharge subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 2 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Eye pruritus subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Eye swelling subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 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 occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 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 occurrences (all) | 0 / 79 (0.00%) 0 | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 26 / 79 (32.91%) 31 | 4 / 40 (10.00%) 5 | 7 / 40 (17.50%) 7 |
| Viral infection subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 2 / 40 (5.00%) 2 |
| Viral pharyngitis subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Viral rash subjects affected / exposed occurrences (all) | 1 / 79 (1.27%) 1 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | 5 / 79 (6.33%) 5 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Wound infection subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Weight gain poor subjects affected / exposed occurrences (all) | 0 / 79 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 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 occurrences (all) | 0 / 82 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 80 (0.00%) 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 occurrences (all) | 0 / 82 (0.00%) 0 | 0 / 77 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 82 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 80 (0.00%) 0 |
| Middle ear effusion subjects affected / exposed occurrences (all) | 0 / 82 (0.00%) 0 | 0 / 77 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Otorrhoea subjects affected / exposed occurrences (all) | 1 / 82 (1.22%) 1 | 0 / 77 (0.00%) 0 | 1 / 80 (1.25%) 1 |
| Tympanic membrane hyperaemia subjects affected / exposed occurrences (all) | 0 / 82 (0.00%) 0 | 0 / 77 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctival haemorrhage subjects affected / exposed occurrences (all) | 0 / 82 (0.00%) 0 | 0 / 77 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Conjunctivitis subjects affected / exposed occurrences (all) | 4 / 82 (4.88%) 4 | 7 / 77 (9.09%) 8 | 2 / 80 (2.50%) 2 |
| Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 82 (0.00%) 0 | 0 / 77 (0.00%) 0 | 0 / 80 (0.00%) 0 |
| Eye discharge subjects affected / exposed occurrences (all) | 0 / 82 (0.00%) 0 | 2 / 77 (2.60%) 2 | 0 / 80 (0.00%) 0 |
| Eye pruritus subjects affected / exposed occurrences (all) | 0 / 82 (0.00%) 0 | 1 / 77 (1.30%) 1 | 1 / 80 (1.25%) 1 |
| Eye swelling subjects affected / exposed occurrences (all) | 0 / 82 (0.00%) 0 | 1 / 77 (1.30%) 1 | 0 / 80 (0.00%) 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 occurrences (all) | 0 / 82 (0.00%) 0 | 0 / 77 (0.00%) 0 | 0 / 80 (0.00%) 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 | | | |

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|-----------------------------|----------------|----------------|----------------|
| 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 | | | |

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

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|--|---------------------|--|--|
| 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 occurrences (all) | 0 / 78 (0.00%) 0 | | |
| General disorders and administration site conditions | | | |

| | | | |
|---|----------------|--|--|
| Feeling hot | | | |
| subjects affected / exposed | 0 / 78 (0.00%) | | |
| occurrences (all) | 0 | | |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 78 (1.28%) | | |
| occurrences (all) | 1 | | |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 78 (0.00%) | | |
| occurrences (all) | 0 | | |
| Irritability | | | |
| subjects affected / exposed | 0 / 78 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain | | | |
| subjects affected / exposed | 1 / 78 (1.28%) | | |
| occurrences (all) | 1 | | |
| Vaccination site pain | | | |
| subjects affected / exposed | 0 / 78 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vessel puncture site haemorrhage | | | |
| subjects affected / exposed | 0 / 78 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immune system disorders | | | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 78 (0.00%) | | |
| occurrences (all) | 0 | | |
| Multiple allergies | | | |
| subjects affected / exposed | 1 / 78 (1.28%) | | |
| occurrences (all) | 1 | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 78 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 78 (0.00%) | | |
| occurrences (all) | 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 occurrences (all) | 2 / 78 (2.56%) 3 | | |
| Cardiac murmur subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Occult blood subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Injury, poisoning and procedural complications | | | |
| Animal bite subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Arthropod bite subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Contusion subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Excoriation subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Gingival injury subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Head injury subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Joint sprain subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Scratch subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 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 occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Middle ear effusion subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Otorrhoea subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Tympanic membrane hyperaemia subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Eye disorders Conjunctival haemorrhage subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 5 / 78 (6.41%) 5 | | |
| Conjunctivitis allergic subjects affected / exposed occurrences (all) | 1 / 78 (1.28%) 1 | | |
| Eye discharge subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Eye pruritus subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 0 | | |
| Eye swelling subjects affected / exposed occurrences (all) | 0 / 78 (0.00%) 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 | | | |

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|-----------------------------|----------------|--|--|
| 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 | | | |

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

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| 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