

## Disclaimer

The FDA chose a specific outcome algorithm that met its need for a given medical product-outcome assessment. The use of a specific outcome algorithm in a Sentinel assessment should not be interpreted as an endorsement from FDA to use the algorithm for all safety assessments. Investigators should always consider the objective, study design, analytic approach, and data source of a given medical product safety assessment when choosing the outcome algorithm. The suitability of an outcome algorithm may change when applied to different scenarios. For additional information, please refer to the <u>Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data</u> guidance document provided by the FDA.



| Overview             |  |  |  |
|----------------------|--|--|--|
| Title                | Intussusception Algorithm Defined in "Intussusception Risk After Rotavirus Vaccination |  |  |
|                      | in U.S. Infants (PRISM)"   |  |  |
| Description          | This report lists International Classification of Diseases, Ninth Edition, Clinical    |  |  |
|                      | Modification (ICD-9-CM) diagnosis codes and Current Procedural Terminology, Fourth     |  |  |
|                      | Edition (CPT-4) and algorithms used to define intussusception in this request.         |  |  |
|                      | For additional information about the algorithm and how it was defined relative to the  |  |  |
|                      | cohort and exposures of interest in the inferential analysis, see the Modular Program  |  |  |
|                      | reports here: https://www.sentinelinitiative.org/vaccines-blood-                       |  |  |
|                      | biologics/assessments/intussusception-risk-after-rotavirus-vaccination-us-infants.     |  |  |
| Outcome              | Intussusception  |  |  |
| Algorithms to Define | Evidence of an ICD-9-CM or CPT-4 code used to define intussuception in the Inpatient   |  |  |
| Outcome              | or Emergency Department care setting in any diagnosis position                         |  |  |



## Glossary

**Care Setting** - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or missing (U)

Outcome - outcome of interest (either primary or secondary)

**Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

**Query Period** - period in which the modular program looks for exposures and outcomes of interest **Request Send Date** - date the request was sent to Sentinel Data Partners



International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) Diagnosis Codes and Current Procedural Terminology, Fourth Edition (CPT-4) Procedure Codes Used to Define Intussusception in this Request

| Codes | Code Type | Description   |
|-------|-----------|---|
| 560.0 | ICD-9-CM  | Intussusception   |
| 543.9 | ICD-9-CM  | Other and unspecified diseases of the appendix, including intussusception |
| 74283 | CPT-4     | Therapeutic enema, contrast or air, for reduction of intussusception or   |
|       |           | other intraluminal obstruction  |