Modular Program Report

Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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CBER_MPL1R_WP005_NSDP_V01

<table>
<tr><td colspan="1">Overview for Request cber_mpl1r_wp005_nsdp_v01</td></tr>
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Request ID: cber_mpl1r_wp005_nsdp_v01

Request Description: This report contains estimates of the number of cases of pertussis among infants under six months of age.

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, Version 3.0.3

Data Source: The request was run against the Sentinel Distributed Database (SDD) for the time period of January 1, 2010 to September 30, 2015 from 16 health plans contributing to the SDD. This request was distributed on August 18, 2016. See Appendix A for a list of the latest dates of available data for each Data Partner.

Study Design: This request was designed to calculate background rates of pertussis. The number of infants with the events of interest were calculated overall and stratified by age group and year-month. Results from health plans with claims data sources and health plans with integrated (claims and electronic medical records) data sources were aggregated separately.

Events of Interest: There were two events of interest: 1) the occurrence of a pertussis diagnosis code and 2) the occurrence of a lab test code followed by a pertussis diagnosis code. Pertussis diagnosis codes were defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes 033.0 and 033.9. A list of Current Procedural Terminology, 4th Edition (CPT-4) procedure codes used to define lab tests can be found in Appendix B.

Cohort Eligibility Criteria and Cohorts of Interest: Infants aged 0-<1 month, 1-<2months, 2-<3 months, 3-<4 months, 4-<5 months, 5-<6 months were included in the cohorts and were required to be enrolled in plans with medical coverage. Only the first event per infant was captured during the study period. A total of 17 cohorts of interest were examined separately and were defined by the occurrence of:

- ICD-9-CM code 033.0 in the ambulatory care setting, emergency department care setting, or inpatient (any diagnosis position) care setting.
- ICD-9-CM code 033.0 or 033.9 in the ambulatory care setting, emergency department care setting, inpatient care setting with a principal diagnosis position, or inpatient (any diagnosis position) care setting.
- A lab test code in any care setting followed by ICD-9-CM code 033.0 in either the:
    - Inpatient care setting with a principal diagnosis position, ambulatory care setting, or emergency department care setting on the day of (day 0) to up to 15 days or 28 days after the lab test code.
    - Ambulatory care setting or emergency department care setting on the day after (day 1) to up to 15 days or 28 days after the lab test code.

Senstivity Analysis Request ID: cber_mpl1r_wp007_nsdp_v01

Senstivity Analysis Request Description: This report also contains estimates of pertussis cases among infants under three months of age from a subset of claims health plans as a sensitivity analysis. Please see Table 4 for a summary of pertussis cases in infants under three months.

Limitations: Algorithms used to define events are imperfect; thus, it is possible that there may be misclassification. Please note that not all Data Partners have data through the end of 2015; therefore, 2015 data should be interpreted with caution. Please see Appendix A for a list of the latest dates of available data for each Data Partner.

Please see the Appendix C for the specifications of parameters used in the analyses for this request.

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Tool*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

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). Along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

    Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters

    Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits

    Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date

    Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays

    Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: (1) 01: Cohort includes only the first valid incident treatment episode during the query period; (2) 02: Cohort includes all valid incident treatment episodes during the query period; (3) 03: Cohort includes all valid incident treatment

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Event Deduplication - specifies how events are counted by the MP algorithm: (0) 0: Counts all occurrences of an HOI during an exposure episode; (1) 1: de-

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode.

Lookback Period (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing condition

Member-Years - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period all divided

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Treatment Episode Truncation Indicator - indicates whether observation of the incident query code during follow-up requires truncation of valid

Users - number of members with exposure during the query period. Member must have no evidence of exposure(s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

Washout Period (drug/exposure) -** number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) -** number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

Table 1: Summary of Pertussis Cases in the Sentinel Distributed Database between January 1, 2010 and September 30, 2015, by Case Definition and Data Source

	Claims-based Data Partners	Data Partners with Integrated Systems
Number of Patients Under Six Months of Age with Medical Coverage from January 2010 to September 2015*		
	7,894,046	697,733

	Number of Infants with a Diagnosis	
Case Definition	**Claims-based Data Partners**	**Data Partners with Integrated Systems**
Pertussis Diagnosis Code 033.0 in Ambulatory Setting		
	910	16
Pertussis Diagnosis Code 033.0 or 033.9 in Ambulatory Setting		
	2,680	215
Pertussis Diagnosis Code 033.0 in Emergency Department Setting		
	65	8
Pertussis Diagnosis Code 033.0 or 033.9 in Emergency Department Setting		
	408	40
Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis		
	155	17
Pertussis Diagnosis Code 033.0 or 033.9 in Inpatient Setting with Principal Diagnosis		
	594	58
Pertussis Diagnosis Code 033.0 or 033.9 in Inpatient Setting		
	1,040	99

	Number of Infants with a Lab Test Followed by a Diagnosis	
Case Definition	**Claims-based Data Partners**	**Data Partners with Integrated Systems**
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 0 to 15 Days		
	407	6
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 0 to 28 Days		
	418	6
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 1 to 15 Days		
	197	4
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 1 to 28 Days		
	209	4
Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 0 to 15 Days		
	32	7
Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 0 to 28 Days		
	33	7
Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 1 to 15 Days		
	11	2
Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 1 to 28 Days		
	12	2
Lab Test followed by Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis within 0 to 15 Days		
	45	11
Lab Test followed by Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis within 0 to 28 Days		
	45	11

* These numbers include all patients who met the age and enrollment requirements during the query period (January 2010 - September 2015). Please interpret these numbers with caution, as patients may be double counted if they were assigned more than one Patient ID shortly after birth.

Table 2: Summary of Pertussis Cases in the Sentinel Distributed Database between January 1, 2010 and September 30, 2015, by Case Definition, Data Source, and Age Group

		Claims-based Data Partners	Data Partners with Integrated Systems
Number of Patients Under Six Months of Age with Medical Coverage from January 2010 to September 2015*			
		7,894,046	697,733
		Number of Infants with a Diagnosis	
		Claims-based Data Partners	Data Partners with Integrated Systems
Case Definition	**Age of Infant**	**Partners**	**Integrated Systems**
Pertussis Diagnosis Code 033.0 in Ambulatory Setting			
	0 to <1 months	43	2
	1 to <2 months	162	2
	2 to <3 months	215	3
	3 to <4 months	173	4
	4 to <5 months	127	2
	5 to <=6 months	190	3
Pertussis Diagnosis Code 033.0 or 033.9 in Ambulatory Setting			
	0 to <1 months	126	11
	1 to <2 months	463	31
	2 to <3 months	576	50
	3 to <4 months	479	45
	4 to <5 months	404	31
	5 to <=6 months	632	47
Pertussis Diagnosis Code 033.0 in Emergency Department Setting			
	0 to <1 months	1	0
	1 to <2 months	9	3
	2 to <3 months	17	2
	3 to <4 months	14	2
	4 to <5 months	12	1
	5 to <6 months	12	0
Pertussis Diagnosis Code 033.0 or 033.9 in Emergency Department Setting			
	0 to <1 months	5	0
	1 to <2 months	75	7
	2 to <3 months	101	9
	3 to <4 months	92	9
	4 to <5 months	66	7
	5 to <=6 months	69	8
Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis			
	0 to <1 months	16	2
	1 to <2 months	51	3
	2 to <3 months	49	5
	3 to <4 months	17	4
	4 to <5 months	14	3
	5 to <=6 months	8	0
Pertussis Diagnosis Code 033.0 or 033.9 in Inpatient Setting with Principal Diagnosis			
	0 to <1 months	43	6
	1 to <2 months	208	14
	2 to <3 months	168	21
	3 to <4 months	87	9
	4 to <5 months	58	5
	5 to <=6 months	30	3

Pertussis Diagnosis Code 033.0 or 033.9 in Inpatient Setting

	0 to <1 months	119	17
	1 to <2 months	341	24
	2 to <3 months	264	30
	3 to <4 months	143	10
	4 to <5 months	88	12
	5 to <=6 months	85	6

Number of Infants with a Lab Test Followed by a Diagnosis

Case Definition		Claims-based Data Partners	Data Partners with Integrated Systems
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 0 to 15 Days			
	0 to <1 months	25	1
	1 to <2 months	59	0
	2 to <3 months	99	0
	3 to <4 months	76	2
	4 to <5 months	57	2
	5 to <=6 months	91	1
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 0 to 28 Days			
	0 to <1 months	25	1
	1 to <2 months	63	0
	2 to <3 months	99	0
	3 to <4 months	80	2
	4 to <5 months	56	2
	5 to <=6 months	95	1
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 1 to 15 Days			
	0 to <1 months	15	1
	1 to <2 months	35	0
	2 to <3 months	54	0
	3 to <4 months	39	2
	4 to <5 months	29	1
	5 to <=6 months	25	0
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 1 to 28 Days			
	0 to <1 months	15	1
	1 to <2 months	39	0
	2 to <3 months	54	0
	3 to <4 months	43	2
	4 to <5 months	29	1
	5 to <=6 months	29	0
Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 0 to 15 Days			
	0 to <1 months	0	0
	1 to <2 months	5	3
	2 to <3 months	9	1
	3 to <4 months	6	1
	4 to <5 months	6	1
	5 to <=6 months	6	1
Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 0 to 28 Days			
	0 to <1 months	0	0
	1 to <2 months	6	3
	2 to <3 months	9	1
	3 to <4 months	6	1
	4 to <5 months	6	1
	5 to <=6 months	6	1

Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 1 to 15 Days		
0 to <1 months	0	0
1 to <2 months	3	0
2 to <3 months	2	0
3 to <4 months	2	0
4 to <5 months	2	1
5 to <=6 months	2	1
Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 1 to 28 Days		
0 to <1 months	0	0
1 to <2 months	4	0
2 to <3 months	2	0
3 to <4 months	2	0
4 to <5 months	2	1
5 to <=6 months	2	1
Lab Test followed by Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis within 0 to 15 Days		
0 to <1 months	4	2
1 to <2 months	16	3
2 to <3 months	13	5
3 to <4 months	2	1
4 to <5 months	7	0
5 to <=6 months	3	0
Lab Test followed by Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis within 0 to 28 Days		
0 to <1 months	4	2
1 to <2 months	16	3
2 to <3 months	13	5
3 to <4 months	2	1
4 to <5 months	7	0
5 to <=6 months	3	0

* These numbers include all patients who met the age and enrollment requirements during the query period (January 2010 - September 2015). Please interpret these numbers with caution, as patients may be double counted if they were assigned more than one Patient ID shortly after birth.

Table 3: Summary of Pertussis Cases in the Sentinel Distributed Database between January 1, 2010 and September 30, 2015, by Case Definition, Data Source, and Year-Month*

	Claims-based Data Partners	Data Partners with Integrated Systems
Number of Patients Under Six Months of Age with Medical Coverage from January 2010 to September 2015**		
	7,894,046	697,733

| | **Number of Infants with a Diagnosis** | |
	Claims-based Data Partners	Data Partners with Integrated Systems
Case Definition		
Pertussis Diagnosis Code 033.0 in Ambulatory Setting		
2010		
January	13	0
February	10	0
March	10	0
April	13	0
May	7	0
June	8	0
July	18	0
August	13	0
September	27	1
October	17	0
November	19	0
December	16	2
2011		
January	14	0
February	22	0
March	11	0
April	13	0
May	10	0
June	9	0
July	6	0
August	12	0
September	15	0
October	9	0
November	12	0
December	10	0
2012		
January	15	0
February	16	2
March	14	1
April	11	1
May	9	0
June	16	0
July	20	0
August	23	2
September	23	0
October	11	0
November	16	0
December	15	0

2013

	January	24	1
	February	11	0
	March	14	1
	April	10	0
	May	17	0
	June	10	0
	July	19	0
	August	16	1
	September	9	0
	October	11	1
	November	12	0
	December	13	0

2014

	January	17	2
	February	14	0
	March	16	0
	April	12	0
	May	14	0
	June	12	0
	July	20	0
	August	20	0
	September	16	0
	October	7	0
	November	8	0
	December	13	1

2015

	January	12	0
	February	14	0
	March	12	0
	April	7	0
	May	2	0
	June	6	0
	July	5	0
	August	4	0
	September	10	0

Pertussis Diagnosis Code 033.0 or 033.9 in Ambulatory Setting

2010

	January	29	0
	February	23	3
	March	31	4
	April	25	2
	May	21	1
	June	34	5
	July	63	10
	August	53	10
	September	64	8
	October	58	6
	November	73	4
	December	66	5

2011

	January	63	4
	February	50	3
	March	42	7
	April	41	2
	May	40	0

	June	37	4
	July	28	2
	August	38	1
	September	29	5
	October	30	1
	November	35	3
	December	42	2
2012			
	January	46	2
	February	47	5
	March	32	5
	April	28	4
	May	38	3
	June	42	5
	July	56	3
	August	58	9
	September	51	4
	October	42	6
	November	57	5
	December	44	2
2013			
	January	58	2
	February	37	1
	March	32	3
	April	28	2
	May	34	1
	June	38	8
	July	41	3
	August	31	3
	September	28	1
	October	34	3
	November	38	0
	December	45	2
2014			
	January	42	6
	February	44	2
	March	33	0
	April	37	0
	May	40	3
	June	43	2
	July	46	2
	August	46	2
	September	36	0
	October	30	2
	November	23	4
	December	45	5
2015			
	January	43	0
	February	35	2
	March	29	0
	April	26	1
	May	14	2
	June	17	4
	July	15	1
	August	16	1
	September	20	2

Pertussis Diagnosis Code 033.0 in Emergency Department Setting

2010			
	January	0	0
	February	0	0
	March	1	0
	April	1	0
	May	0	0
	June	0	0
	July	0	0
	August	1	0
	September	2	0
	October	1	0
	November	1	0
	December	1	0
2011			
	January	0	0
	February	0	0
	March	1	0
	April	1	0
	May	0	0
	June	1	0
	July	0	0
	August	1	0
	September	1	0
	October	0	0
	November	0	0
	December	2	0
2012			
	January	1	0
	February	1	0
	March	1	0
	April	1	1
	May	1	1
	June	2	0
	July	1	0
	August	2	1
	September	3	0
	October	1	0
	November	0	0
	December	0	0
2013			
	January	0	0
	February	2	0
	March	0	1
	April	0	0
	May	2	0
	June	1	0
	July	5	0
	August	2	0
	September	1	0
	October	3	0
	November	0	0
	December	2	0
2014			
	January	2	0
	February	1	0

March	0	0
April	2	0
May	1	0
June	2	0
July	5	0
August	2	0
September	0	0
October	0	0
November	1	2
December	1	0
2015		
January	0	0
February	0	1
March	0	0
April	0	0
May	0	1
June	0	0
July	0	0
August	0	0
September	1	0

Pertussis Diagnosis Code 033.0 or 033.9 in Emergency Department Setting

2010		
January	5	0
February	2	1
March	5	0
April	7	1
May	5	0
June	4	1
July	6	2
August	6	1
September	8	0
October	8	2
November	3	0
December	7	0
2011		
January	2	1
February	6	0
March	5	1
April	10	0
May	5	0
June	5	0
July	5	0
August	3	0
September	9	0
October	8	1
November	3	0
December	8	0
2012		
January	6	0
February	6	2
March	3	0
April	4	1
May	9	1
June	6	1
July	12	0
August	3	2

	September	13	2
	October	6	0
	November	9	1
	December	6	1
2013			
	January	9	1
	February	9	1
	March	9	3
	April	2	0
	May	8	1
	June	7	0
	July	8	0
	August	11	0
	September	4	0
	October	9	0
	November	3	0
	December	7	0
2014			
	January	8	1
	February	5	1
	March	4	0
	April	5	0
	May	7	0
	June	6	0
	July	11	0
	August	6	0
	September	3	0
	October	3	0
	November	5	2
	December	11	1
2015			
	January	5	2
	February	1	1
	March	2	1
	April	5	0
	May	4	1
	June	4	1
	July	5	0
	August	3	1
	September	1	0

Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis

2010			
	January	2	0
	February	2	0
	March	4	1
	April	0	1
	May	3	1
	June	4	0
	July	7	1
	August	4	0
	September	3	0
	October	1	1
	November	1	0
	December	1	1

Year	Month		
2011			
	January	1	1
	February	1	0
	March	1	0
	April	1	0
	May	2	0
	June	2	0
	July	1	0
	August	4	0
	September	4	1
	October	3	0
	November	2	1
	December	0	0
2012			
	January	5	0
	February	1	0
	March	1	1
	April	3	0
	May	2	0
	June	5	0
	July	0	0
	August	4	0
	September	2	0
	October	8	2
	November	4	1
	December	1	1
2013			
	January	2	0
	February	4	0
	March	2	1
	April	0	0
	May	3	0
	June	5	0
	July	3	0
	August	3	0
	September	1	1
	October	2	0
	November	4	0
	December	3	0
2014			
	January	1	0
	February	2	0
	March	2	0
	April	1	0
	May	3	0
	June	3	0
	July	6	0
	August	3	0
	September	4	0
	October	0	0
	November	2	1
	December	0	0
2015			
	January	1	0
	February	0	0
	March	1	0

	April	1	0
	May	1	0
	June	0	0
	July	0	0
	August	0	0
	September	2	0

Pertussis Diagnosis Code 033.0 or 033.9 in Inpatient Setting with Principal Diagnosis

2010			
	January	9	0
	February	4	1
	March	14	2
	April	8	1
	May	13	1
	June	11	3
	July	17	5
	August	15	2
	September	8	1
	October	8	1
	November	4	0
	December	12	1
2011			
	January	11	2
	February	5	0
	March	6	1
	April	8	0
	May	7	0
	June	10	1
	July	7	1
	August	10	0
	September	13	1
	October	7	0
	November	5	2
	December	5	0
2012			
	January	9	1
	February	9	1
	March	7	1
	April	9	0
	May	11	0
	June	17	0
	July	19	0
	August	15	1
	September	13	1
	October	17	2
	November	12	2
	December	4	1
2013			
	January	10	0
	February	7	0
	March	7	1
	April	7	1
	May	8	0
	June	13	2
	July	13	1
	August	11	1
	September	11	4

	October	6	0
	November	10	2
	December	6	2
2014			
	January	4	0
	February	7	0
	March	7	0
	April	9	0
	May	9	2
	June	12	1
	July	17	0
	August	11	0
	September	8	0
	October	3	0
	November	7	1
	December	5	0
2015			
	January	4	0
	February	4	0
	March	3	1
	April	4	1
	May	1	0
	June	3	1
	July	3	0
	August	2	1
	September	3	0

Pertussis Diagnosis Code 033.0 or 033.9 in Inpatient Setting

2010			
	January	18	1
	February	14	1
	March	20	5
	April	16	1
	May	19	2
	June	13	3
	July	22	5
	August	18	3
	September	15	1
	October	13	3
	November	11	0
	December	28	2
2011			
	January	23	2
	February	13	1
	March	25	2
	April	17	0
	May	10	1
	June	13	1
	July	9	1
	August	13	0
	September	16	3
	October	16	0
	November	8	3
	December	13	1
2012			
	January	18	1
	February	20	1

March	16	2
April	17	0
May	16	0
June	21	1
July	26	1
August	21	1
September	23	1
October	23	2
November	21	3
December	17	3
2013		
January	25	0
February	17	1
March	13	3
April	16	1
May	15	2
June	16	2
July	18	2
August	15	1
September	20	5
October	12	0
November	17	3
December	12	5
2014		
January	11	1
February	13	0
March	17	2
April	12	2
May	12	2
June	14	1
July	22	0
August	13	1
September	11	0
October	7	0
November	14	1
December	12	0
2015		
January	12	1
February	6	1
March	10	1
April	10	1
May	7	0
June	5	1
July	7	0
August	3	1
September	4	0

	Number of Infants with a Lab Test Followed by a	
Case Definition	**Claims-based Data Partners**	**Data Partners with Integrated Systems**
Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 0 to 15 Days		
2010		
January	4	0
February	3	0
March	2	0
April	4	0

	May	4	0
	June	3	0
	July	7	0
	August	4	0
	September	10	1
	October	6	0
	November	11	0
	December	7	1
2011			
	January	4	0
	February	11	0
	March	8	0
	April	7	0
	May	7	0
	June	2	0
	July	4	0
	August	5	0
	September	5	0
	October	3	0
	November	7	0
	December	3	0
2012			
	January	3	0
	February	6	0
	March	5	1
	April	4	0
	May	4	0
	June	8	0
	July	8	0
	August	11	1
	September	10	0
	October	5	0
	November	11	0
	December	7	0
2013			
	January	12	0
	February	5	0
	March	8	0
	April	6	0
	May	6	0
	June	3	0
	July	10	0
	August	5	1
	September	4	0
	October	8	0
	November	4	0
	December	7	0
2014			
	January	10	0
	February	7	0
	March	12	0
	April	8	0
	May	8	0
	June	2	0
	July	7	0
	August	11	0

September	6	0
October	5	0
November	3	0
December	5	1
2015		
January	5	0
February	5	0
March	6	0
April	3	0
May	1	0
June	3	0
July	1	0
August	2	0
September	6	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 0 to 28 Days

2010		
January	4	0
February	3	0
March	3	0
April	4	0
May	4	0
June	3	0
July	7	0
August	5	0
September	10	1
October	6	0
November	11	0
December	7	1
2011		
January	4	0
February	11	0
March	8	0
April	8	0
May	8	0
June	2	0
July	4	0
August	5	0
September	5	0
October	6	0
November	7	0
December	3	0
2012		
January	3	0
February	6	0
March	5	1
April	4	0
May	4	0
June	9	0
July	7	0
August	11	1
September	10	0
October	6	0
November	10	0
December	7	0

2013			
	January	12	0
	February	5	0
	March	8	0
	April	6	0
	May	6	0
	June	3	0
	July	11	0
	August	5	1
	September	4	0
	October	8	0
	November	4	0
	December	7	0
2014			
	January	10	0
	February	7	0
	March	12	0
	April	8	0
	May	8	0
	June	3	0
	July	7	0
	August	12	0
	September	6	0
	October	5	0
	November	3	0
	December	6	1
2015			
	January	5	0
	February	5	0
	March	6	0
	April	3	0
	May	1	0
	June	3	0
	July	1	0
	August	2	0
	September	6	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 1 to 15 Days

2010			
	January	2	0
	February	2	0
	March	2	0
	April	3	0
	May	1	0
	June	1	0
	July	2	0
	August	3	0
	September	4	0
	October	2	0
	November	7	0
	December	6	1
2011			
	January	1	0
	February	7	0
	March	3	0
	April	5	0
	May	3	0

	June	0	0
	July	2	0
	August	3	0
	September	3	0
	October	2	0
	November	2	0
	December	0	0
2012			
	January	1	0
	February	2	0
	March	1	0
	April	3	0
	May	1	0
	June	3	0
	July	6	0
	August	4	1
	September	5	0
	October	1	0
	November	5	0
	December	1	0
2013			
	January	7	0
	February	2	0
	March	3	0
	April	3	0
	May	1	0
	June	2	0
	July	7	0
	August	5	1
	September	3	0
	October	5	0
	November	1	0
	December	4	0
2014			
	January	4	0
	February	3	0
	March	8	0
	April	3	0
	May	6	0
	June	1	0
	July	3	0
	August	3	0
	September	3	0
	October	3	0
	November	1	0
	December	2	1
2015			
	January	3	0
	February	4	0
	March	1	0
	April	0	0
	May	0	0
	June	2	0
	July	1	0
	August	1	0
	September	3	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Ambulatory Setting within 1 to 28 Days

2010			
	January	2	0
	February	2	0
	March	3	0
	April	3	0
	May	1	0
	June	1	0
	July	2	0
	August	4	0
	September	4	0
	October	2	0
	November	7	0
	December	6	1
2011			
	January	1	0
	February	7	0
	March	3	0
	April	6	0
	May	4	0
	June	0	0
	July	2	0
	August	3	0
	September	3	0
	October	5	0
	November	2	0
	December	0	0
2012			
	January	1	0
	February	2	0
	March	1	0
	April	3	0
	May	1	0
	June	4	0
	July	5	0
	August	4	1
	September	5	0
	October	2	0
	November	5	0
	December	1	0
2013			
	January	7	0
	February	2	0
	March	3	0
	April	3	0
	May	1	0
	June	2	0
	July	8	0
	August	5	1
	September	3	0
	October	5	0
	November	1	0
	December	4	0
2014			
	January	4	0
	February	3	0

	March	8	0
	April	3	0
	May	6	0
	June	2	0
	July	3	0
	August	4	0
	September	3	0
	October	3	0
	November	1	0
	December	3	1
2015			
	January	3	0
	February	4	0
	March	1	0
	April	0	0
	May	0	0
	June	2	0
	July	1	0
	August	1	0
	September	3	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 0 to 15 Days

2010			
	January	0	0
	February	0	0
	March	0	0
	April	0	0
	May	0	0
	June	0	0
	July	0	0
	August	0	0
	September	0	0
	October	1	0
	November	1	0
	December	1	0
2011			
	January	0	0
	February	0	0
	March	0	0
	April	0	0
	May	0	0
	June	0	0
	July	0	0
	August	0	0
	September	1	0
	October	0	0
	November	0	0
	December	1	0
2012			
	January	1	0
	February	0	0
	March	1	0
	April	1	1
	May	2	0
	June	1	0
	July	1	0
	August	2	1

	September	1	0
	October	0	0
	November	0	0
	December	0	0
2013			
	January	1	0
	February	0	0
	March	0	0
	April	0	0
	May	0	0
	June	1	0
	July	2	0
	August	1	0
	September	1	0
	October	1	0
	November	0	0
	December	1	0
2014			
	January	1	0
	February	0	0
	March	0	1
	April	1	0
	May	0	0
	June	1	0
	July	4	0
	August	1	0
	September	0	0
	October	0	0
	November	0	2
	December	1	0
2015			
	January	0	0
	February	0	1
	March	0	0
	April	0	1
	May	0	0
	June	0	0
	July	0	0
	August	0	0
	September	0	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 0 to 28 Days

2010			
	January	0	0
	February	0	0
	March	0	0
	April	0	0
	May	0	0
	June	0	0
	July	0	0
	August	0	0
	September	0	0
	October	1	0
	November	1	0
	December	1	0

2011			
	January	0	0
	February	0	0
	March	0	0
	April	0	0
	May	0	0
	June	0	0
	July	0	0
	August	0	0
	September	1	0
	October	0	0
	November	0	0
	December	1	0
2012			
	January	1	0
	February	0	0
	March	1	0
	April	1	1
	May	2	0
	June	1	0
	July	1	0
	August	2	1
	September	1	0
	October	0	0
	November	0	0
	December	0	0
2013			
	January	1	0
	February	0	0
	March	0	0
	April	0	0
	May	0	0
	June	1	0
	July	2	0
	August	1	0
	September	1	0
	October	1	0
	November	0	0
	December	1	0
2014			
	January	1	0
	February	1	0
	March	0	1
	April	1	0
	May	0	0
	June	1	0
	July	4	0
	August	1	0
	September	0	0
	October	0	0
	November	0	2
	December	1	0
2015			
	January	0	0
	February	0	1
	March	0	0

April	0	1
May	0	0
June	0	0
July	0	0
August	0	0
September	0	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 1 to 15 Days

2010		
January	0	0
February	0	0
March	0	0
April	0	0
May	0	0
June	0	0
July	0	0
August	0	0
September	0	0
October	0	0
November	0	0
December	0	0
2011		
January	0	0
February	0	0
March	0	0
April	0	0
May	0	0
June	0	0
July	0	0
August	0	0
September	0	0
October	0	0
November	0	0
December	0	0
2012		
January	0	0
February	0	0
March	0	0
April	0	0
May	2	0
June	0	0
July	1	0
August	2	0
September	0	0
October	0	0
November	0	0
December	0	0
2013		
January	1	0
February	0	0
March	0	0
April	0	0
May	0	0
June	0	0
July	1	0
August	1	0
September	1	0

October	0	0
November	0	0
December	1	0
2014		
January	0	0
February	0	0
March	0	1
April	0	0
May	0	0
June	0	0
July	0	0
August	0	0
September	0	0
October	0	0
November	0	0
December	1	0
2015		
January	0	0
February	0	0
March	0	0
April	0	1
May	0	0
June	0	0
July	0	0
August	0	0
September	0	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Emergency Department Setting within 1 to 28 Days

2010		
January	0	0
February	0	0
March	0	0
April	0	0
May	0	0
June	0	0
July	0	0
August	0	0
September	0	0
October	0	0
November	0	0
December	0	0
2011		
January	0	0
February	0	0
March	0	0
April	0	0
May	0	0
June	0	0
July	0	0
August	0	0
September	0	0
October	0	0
November	0	0
December	0	0
2012		
January	0	0
February	0	0

	March	0	0
	April	0	0
	May	2	0
	June	0	0
	July	1	0
	August	2	0
	September	0	0
	October	0	0
	November	0	0
	December	0	0
2013			
	January	1	0
	February	0	0
	March	0	0
	April	0	0
	May	0	0
	June	0	0
	July	1	0
	August	1	0
	September	1	0
	October	0	0
	November	0	0
	December	1	0
2014			
	January	0	0
	February	1	0
	March	0	1
	April	0	0
	May	0	0
	June	0	0
	July	0	0
	August	0	0
	September	0	0
	October	0	0
	November	0	0
	December	1	0
2015			
	January	0	0
	February	0	0
	March	0	0
	April	0	1
	May	0	0
	June	0	0
	July	0	0
	August	0	0
	September	0	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis within 0 to 15 Days

2010			
	January	1	0
	February	0	0
	March	1	1
	April	0	1
	May	1	1
	June	0	0
	July	5	0
	August	3	0

	September	1	0
	October	0	1
	November	1	0
	December	0	1
2011			
	January	0	1
	February	0	0
	March	0	0
	April	1	0
	May	0	0
	June	1	0
	July	0	0
	August	0	1
	September	0	0
	October	1	0
	November	0	0
	December	0	0
2012			
	January	0	0
	February	0	0
	March	0	1
	April	0	0
	May	0	0
	June	0	0
	July	0	0
	August	1	0
	September	0	0
	October	3	0
	November	2	1
	December	1	0
2013			
	January	0	0
	February	0	0
	March	0	0
	April	0	0
	May	1	0
	June	2	0
	July	1	0
	August	2	0
	September	0	1
	October	1	0
	November	1	0
	December	1	0
2014			
	January	0	0
	February	1	0
	March	1	0
	April	1	0
	May	3	0
	June	1	0
	July	3	0
	August	0	0
	September	2	0
	October	0	0
	November	0	1
	December	0	0

2015		
January	0	0
February	0	0
March	0	0
April	1	0
May	0	0
June	0	0
July	0	0
August	0	0
September	0	0

Lab Test followed by Pertussis Diagnosis Code 033.0 in Inpatient Setting with Principal Diagnosis within 0 to 28 Days

2010		
January	1	0
February	0	0
March	1	1
April	0	1
May	1	1
June	0	0
July	5	0
August	3	0
September	1	0
October	0	1
November	1	0
December	0	1
2011		
January	0	1
February	0	0
March	0	0
April	1	0
May	0	0
June	1	0
July	0	0
August	0	1
September	0	0
October	1	0
November	0	0
December	0	0
2012		
January	0	0
February	0	0
March	0	1
April	0	0
May	0	0
June	0	0
July	0	0
August	1	0
September	0	0
October	3	0
November	2	1
December	1	0
2013		
January	0	0
February	0	0
March	0	0
April	0	0
May	1	0

	June	2	0
	July	1	0
	August	2	0
	September	0	1
	October	1	0
	November	1	0
	December	1	0
2014			
	January	0	0
	February	1	0
	March	1	0
	April	1	0
	May	3	0
	June	1	0
	July	3	0
	August	0	0
	September	2	0
	October	0	0
	November	0	1
	December	0	0
2015			
	January	0	0
	February	0	0
	March	0	0
	April	1	0
	May	0	0
	June	0	0
	July	0	0
	August	0	0
	September	0	0

* Please note that not all Data Partners have data through the end of 2015; therefore, 2015 data should be interpreted with caution. Please see

** These numbers include all patients who met the age and enrollment requirements during the query period (January 2010 - September 2015).
Please interpret these numbers with caution, as patients may be double counted if they were assigned more than one Patient ID shortly after birth.

Table 4: Summary of Pertussis Cases in Infants Under Three Months in the Sentinel Distributed Database between January 1, 2010 and September 30, 2015 among Subset of Claims Data Partners

	Six Data Partners
Number of Patients Under Three Months of Age with Medical Coverage from January 2010 to September 2015 *	
	4,160,665

	Number of Infants with a Diagnosis
Case Definition	**Six Data Partners**
Pertussis Diagnosis Code 033.0 or 033.9 in Inpatient Setting	
	708

* These numbers include all patients who met the age and enrollment requirements during the query period (January 2010 - September 2015). Please interpret these numbers with caution, as patients may be double counted if they were assigned more than one Patient ID shortly after birth.

Appendix A: Latest Date of Available Data for Each Data Partner up to Request End Date (9/30/2015)

Data Source = Claims

DP ID	End Date
DP0001	6/30/2015
DP0002	6/30/2015
DP0003	9/30/2015
DP0004	9/30/2015
DP0005	9/30/2015
DP0006	12/31/2014
DP0007	9/30/2015

Data Source = Integrated

DP ID	End Date
DP0008	6/30/2012
DP0009	9/30/2015
DP0010	5/31/2015
DP0011	9/30/2015
DP0012	9/30/2015
DP0013	9/30/2015
DP0014	9/30/2015
DP0015	9/30/2015
DP0016	9/30/2015

Appendix B: List of Current Procedural Terminology, 4th Edition (CPT-4) Procedure Codes Used to Define Lab Test Events in this Request

CPT-4 Code	Description
83902	Molecular diagnostics; reverse transcription
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87081	Culture, presumptive, pathogenic organisms, screening only;
87140	Culture, typing; immunofluorescent method, each antiserum
87143	Culture, typing; gas liquid chromatography (GLC) or high pressure liquid chromatography (HPLC) method
87147	Culture, typing; immunologic method, other than immunofluorescence (eg agglutination grouping), per antiserum
87149	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed
87265	Infectious agent antigen detection by immunofluorescent technique; Bordetella pertussis/parapertussis
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism

Appendix C: Specifications for Request ID: cber_mpl1r_wp005_nsdp_v01

The Center for Biologics Evaluation and Research requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool, Version 3.0.3, to investigate cases of pertussis among infants aged 0 to 6 months in the Sentinel Distributed Database (SDD).

Query Period January 1st, 2010 - September 30th, 2015 (Results by year-month)
Enrollment Requirement 0 days
Enrollment Gap N/A
Coverage Type Medical coverage
Age Groups 0-<1 month,1-<2months, 2-<3 months, 3-<4 months, 4-<5 months, 5-<6 months, and all ages (0-6 months)
Results Aggregate results for claims and integrated data sources separately

		Event				Inclusion		
Scenario	**Event**	**Care Setting/ Principal Diagnosis Position (PDX)**	**Washout**	**Cohort Definition**	**Inclusion**	**Care Setting/ PDX**	**Lookback Period**
1	Pertussis diagnosis (only code 033.0)	Inpatient w/ Principal Diagnosis	0 days	Include the first event during the query period			
2	Pertussis diagnosis (only code 033.0)	Ambulatory	0 days	Include the first event during the query period			
3	Pertussis diagnosis (only code 033.0)	Emergency Dept.	0 days	Include the first event during the query period			
4	Pertussis diagnosis (code 033.0 or 033.9)	Inpatient	0 days	Include the first event during the query period			
5	Pertussis diagnosis (code 033.0 or 033.9)	Inpatient w/ Principal Diagnosis	0 days	Include the first event during the query period			
6	Pertussis diagnosis (code 033.0 or 033.9)	Ambulatory	0 days	Include the first event during the query period			
7	Pertussis diagnosis (code 033.0 or 033.9)	Emergency Dept.	0 days	Include the first event during the query period			
8	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Inpatient w/ Principal Diagnosis	0 to 15 days after CPT Code Lab Test
9	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Inpatient w/ Principal Diagnosis	0 to 28 days after CPT Code Lab Test
10	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Ambulatory	1 to 15 days after CPT Code Lab Test

11	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Ambulatory	1 to 28 days after CPT Code Lab Test
12	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Ambulatory	0 to 15 days after CPT Code Lab Test
13	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Ambulatory	0 to 28 days after CPT Code Lab Test
14	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Emergency Department	1 to 15 days after CPT Code Lab Test
15	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Emergency Department	1 to 28 days after CPT Code Lab Test
16	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Emergency Department	0 to 15 days after CPT Code Lab Test
17	CPT Code Lab Test	Any Care Setting	0 days	Include the first event during the query period	Pertussis diagnosis (only code 033.0)	Emergency Department	0 to 28 days after CPT Code Lab Test

Note: International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology (CPT) codes were provided by Optum360.