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The following report 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, post market 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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Overview for Request cder_mpl1r_wp087, Report 2

Request ID: cder_mpl1r_wp087

Request Description: The goal of this request was to obtain counts of individuals with well child visits in the Sentinel Distributed Database (SDD). This is report 2 of 2. Report 1 examined the distribution of time between patients' first new central precocious puberty (CPP) diagnosis and Lupron Depot-Ped utilization in the SDD.

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis tool, version 5.2.1

Data Source: Data from January 1, 2000 to October 31, 2017 from 17 Data Partners contributing to the SDD were included in this report. This request was distributed to Data Partners on March 29, 2018. Please see Appendix A for a list of the latest dates of available data for each Data Partner.

Study Design: This request used a cross-sectional design. This request was designed to obtain counts of individuals with a first, second, and third well child visit in the SDD. Results of the analysis were stratified by sex, sex and age group, and sex and year.

Event of Interest: The event of interest was member's first qualifying well child visit that occurred between January 1, 2000 and October 31, 2017. Well child visits were defined using Current Procedural Terminology, Fourth Edition (CPT-4), and International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM, and ICD-10-CM) procedure and diagnosis codes. Please see Appendix B for specific diagnosis and procedure codes used to define well child visits in this report.

Cohort Eligibility Criteria: Members included in the cohort were required to be continuously enrolled in plans with medical and drug coverage for at least 183 days prior to their index visit, during which gaps in coverage of up to 45 days were allowed. Well child visits were assessed using individual member's entire enrollment history. Members of the following age groups on the day of index visit were included in the cohort: 0-4, 5-6, 7-8, 9-10, 11-12, and 13-18 years.

Follow-Up Time: Follow-up began on the day of the first event of interest and continued until the first occurrence of any of the following: 1) disenrollment; 2) the end date of the data provided by each Data Partner (see Appendix A); 3) death.

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

Limitations: Algorithms to define events may not have been validated. Measures in this request are subject to misclassification.

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.

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 Sentinel Common Data Model.

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.

Code Days - indicates the number of times a condition occurs in a member's enrollment history during the lookback period. Multiple codes identified on the same day will only count once (i.e., count code days and not code instances).

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

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

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

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

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 episode.

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-duplicates occurrences of the same HOI code and code type on the same day; (2) 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions days are added after any episode gaps have been bridged.

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

Lookback Period (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

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 by 365.25.

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. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

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.

Treatment Episode Truncation Indicator - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.

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 Well Child Visits in the Sentinel Distributed Database (SDD) between January 1, 2000 and October 31, 2017, Overall

Well Child Visit	Members with Well Child Visits	Eligible Members	Incidence per 1,000 Eligible Members
First	21,484,620	35,368,172	607.46
Second	16,357,664	24,979,121	654.85
Third	12,096,367	17,008,358	711.20

Table 2. Summary of Well Child Visits in the Sentinel Distributed Database (SDD) between January 1, 2000 and October 31, 2017, by Sex

	Members with Well Child Visits	Eligible Members	Incidence per 1,000 Eligible Members
First Well Child Visit			
Female	10,665,618	17,304,371	616.35
Male	10,818,148	18,061,885	598.95
Second Well Child Visit			
Female	8,119,265	12,399,911	654.78
Male	8,237,804	12,578,127	654.93
Third Well Child Visit			
Female	5,992,299	8,447,986	709.32
Male	6,103,673	8,559,729	713.07

Table 3. Summary of Well Child Visits in the Sentinel Distributed Database (SDD) between January 1, 2000 and October 31, 2017, by Sex and Age Group

	Members with Well Child Visits	Eligible Members	Incidence per 1,000 Eligible Members
First Well Child Visit			
Female			
0-4 years	4,273,417	5,874,012	727.51
5-6 years	942,371	2,293,442	410.90
7-8 years	786,602	2,477,158	317.54
9-10 years	828,482	2,680,704	309.05
11-12 years	1,148,556	2,788,300	411.92
13-18 years	2,686,190	6,130,914	438.14
Male			
0-4 years	4,495,240	6,174,805	728.00
5-6 years	1,003,013	2,400,344	417.86
7-8 years	838,319	2,573,818	325.71
9-10 years	879,949	2,783,688	316.11
11-12 years	1,184,159	2,885,668	410.36
13-18 years	2,417,468	6,343,927	381.07
Second Well Child Visit			
Female			
0-4 years	3,713,042	5,051,920	734.98
5-6 years	690,687	1,732,026	398.77
7-8 years	513,751	1,534,822	334.73
9-10 years	534,076	1,600,042	333.79
11-12 years	732,714	1,989,293	368.33
13-18 years	1,934,995	3,945,558	490.42
Male			
0-4 years	3,910,813	5,314,044	735.94
5-6 years	737,614	1,828,143	403.48
7-8 years	549,332	1,622,772	338.51
9-10 years	569,363	1,689,896	336.92
11-12 years	763,204	2,065,454	369.51
13-18 years	1,707,478	3,667,561	465.56

Table 3. Summary of Well Child Visits in the Sentinel Distributed Database (SDD) between January 1, 2000 and October 31, 2017, by Sex and Age Group

	Members with Well Child Visits	Eligible Members	Incidence per 1,000 Eligible Members
Third Well Child Visit			
Female			
0-4 years	3,107,391	3,933,785	789.92
5-6 years	445,586	1,066,278	417.89
7-8 years	340,604	901,586	377.78
9-10 years	338,280	905,096	373.75
11-12 years	446,772	1,122,543	398.00
13-18 years	1,313,666	2,462,502	533.47
Male			
0-4 years	3,274,925	4,142,232	790.62
5-6 years	473,625	1,129,940	419.16
7-8 years	364,697	958,930	380.32
9-10 years	360,501	960,463	375.34
11-12 years	465,016	1,173,572	396.24
13-18 years	1,164,909	2,240,875	519.85

Table 4. Summary of Well Child Visits in the Sentinel Distributed Database (SDD) between January 1, 2000 and October 31, 2017, by Sex and Year

	Members with Well Child Visits	Eligible Members	Incidence per 1,000 Eligible Members
First Well Child Visit			
Female			
2000	196,162	967,426	202.77
2001	269,973	888,106	303.99
2002	201,156	683,829	294.16
2003	157,741	553,977	284.74
2004	155,356	533,393	291.26
2005	135,489	501,294	270.28
2006	512,479	1,869,043	274.19
2007	596,762	1,919,053	310.97
2008	1,264,343	4,175,472	302.80
2009	1,257,328	3,538,764	355.30
2010	876,879	2,694,752	325.40
2011	780,022	2,306,854	338.13
2012	770,500	2,214,913	347.87
2013	821,374	2,302,596	356.72
2014	817,109	2,261,336	361.34
2015	786,930	2,143,174	367.18
2016	777,073	2,121,779	366.24
2017	288,942	1,276,243	226.40
Male			
2000	197,830	1,008,561	196.15
2001	268,619	928,246	289.38
2002	199,197	720,747	276.38
2003	157,959	584,721	270.14
2004	156,339	561,005	278.68
2005	138,358	527,112	262.48
2006	523,430	1,957,078	267.45
2007	595,283	2,013,922	295.58
2008	1,273,853	4,384,275	290.55
2009	1,268,485	3,734,523	339.66
2010	886,909	2,847,214	311.50
2011	790,413	2,430,027	325.27
2012	787,138	2,328,607	338.03
2013	841,103	2,418,250	347.81
2014	838,006	2,371,677	353.34
2015	804,927	2,245,752	358.42
2016	797,063	2,224,545	358.30
2017	293,236	1,339,955	218.84

Table 4. Summary of Well Child Visits in the Sentinel Distributed Database (SDD) between January 1, 2000 and October 31, 2017, by Sex and Year

	Members with Well Child Visits	Eligible Members	Incidence per 1,000 Eligible Members
Second Well Child Visit			
Female			
2000	59,418	348,533	170.48
2001	163,287	513,725	317.85
2002	160,145	508,270	315.08
2003	146,803	463,215	316.92
2004	137,701	438,338	314.14
2005	118,573	414,514	286.05
2006	248,649	1,039,865	239.12
2007	471,343	1,295,873	363.73
2008	661,089	2,494,048	265.07
2009	1,029,056	2,649,279	388.43
2010	759,819	2,101,084	361.63
2011	662,069	1,834,402	360.92
2012	615,569	1,763,222	349.12
2013	674,999	1,821,680	370.54
2014	674,608	1,784,707	377.99
2015	655,418	1,711,362	382.98
2016	632,054	1,679,456	376.34
2017	248,665	1,004,115	247.65
Male			
2000	58,182	350,206	166.14
2001	163,952	516,220	317.60
2002	158,984	512,443	310.25
2003	147,606	472,316	312.52
2004	139,286	449,219	310.06
2005	121,254	426,937	284.01
2006	250,333	1,064,763	235.11
2007	474,645	1,316,982	360.40
2008	653,006	2,526,274	258.49
2009	1,043,815	2,701,434	386.39
2010	773,336	2,151,241	359.48
2011	670,868	1,879,846	356.87
2012	627,965	1,815,759	345.84
2013	690,382	1,880,677	367.09
2014	692,805	1,839,018	376.73
2015	669,750	1,764,524	379.56
2016	648,357	1,732,613	374.21
2017	253,278	1,035,776	244.53

Table 4. Summary of Well Child Visits in the Sentinel Distributed Database (SDD) between January 1, 2000 and October 31, 2017, by Sex and Year

	Members with Well Child Visits	Eligible Members	Incidence per 1,000 Eligible Members
Third Well Child Visit			
Female			
2000	31,262	77,293	404.46
2001	67,669	209,221	323.43
2002	113,449	289,622	391.71
2003	110,227	303,704	362.94
2004	111,863	309,470	361.47
2005	96,983	297,618	325.86
2006	186,217	453,377	410.73
2007	232,846	716,107	325.16
2008	494,976	1,136,496	435.53
2009	528,679	1,552,147	340.61
2010	665,140	1,565,661	424.83
2011	552,519	1,351,229	408.90
2012	510,043	1,238,180	411.93
2013	504,641	1,267,138	398.25
2014	539,875	1,286,055	419.79
2015	532,443	1,249,867	426.00
2016	514,825	1,205,694	426.99
2017	198,642	722,509	274.93
Male			
2000	31,845	75,015	424.52
2001	66,179	208,171	317.91
2002	115,356	290,296	397.37
2003	111,592	306,517	364.06
2004	113,273	315,226	359.34
2005	99,377	306,446	324.29
2006	191,665	461,328	415.46
2007	229,916	723,074	317.97
2008	502,264	1,137,135	441.69
2009	523,851	1,568,168	334.05
2010	682,491	1,607,977	424.44
2011	565,285	1,385,359	408.04
2012	523,377	1,270,769	411.86
2013	514,948	1,300,911	395.84
2014	553,418	1,326,138	417.32
2015	547,728	1,287,348	425.47
2016	528,875	1,242,048	425.81
2017	202,233	743,231	272.10

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (March 29, 2018)

DP ID	DP Start Date[1]	DP End Date[1]
DP01	01/01/2004	10/31/2017
DP02	01/01/2000	08/31/2017
DP03	01/01/2005	08/25/2017
DP04	01/01/2000	07/31/2017
DP05	01/01/2000	07/31/2017
DP06	06/01/2007	07/31/2017
DP07	01/01/2006	07/31/2017
DP08	01/01/2000	07/31/2017
DP09	01/01/2008	06/30/2017
DP10	01/01/2000	06/30/2017
DP11	01/01/2008	03/31/2017
DP12	01/01/2000	12/31/2016
DP13	01/01/2012	06/30/2016
DP14	01/01/2010	12/31/2015
DP15	01/01/2000	10/31/2015
DP16	01/01/2000	05/31/2015
DP17	01/01/2000	10/31/2014

[1]The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Well Child Visits in this Request

Code	Description	Code Type	Code Category
99381	Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; infant (age younger than 1 year)	CPT-4	Procedure
99382	Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; early childhood (age 1 through 4 years)	CPT-4	Procedure
99383	Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; late childhood (age 5 through 11 years)	CPT-4	Procedure
99384	Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; adolescent (age 12 through 17 years)	CPT-4	Procedure
99385	Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; 18-39 years	CPT-4	Procedure
99391	Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; infant (age younger than 1 year)	CPT-4	Procedure
99392	Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; early childhood (age 1 through 4 years)	CPT-4	Procedure
99393	Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; late childhood (age 5 through 11 years)	CPT-4	Procedure

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Well Child Visits in this Request

Code	Description	Code Type	Code Category
99394	Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; adolescent (age 12 through 17 years)	CPT-4	Procedure
99395	Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; 18-39 years	CPT-4	Procedure
V20.2	Routine infant or child health check	ICD-9-CM	Diagnosis
Z00.121	Encounter for routine child health examination with abnormal findings	ICD-10-CM	Diagnosis
Z00.129	Encounter for routine child health examination without abnormal findings	ICD-10-CM	Diagnosis

Appendix C. Specifications Defining Parameters in this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.2.1, to obtain counts of individuals with well child visits in the Sentinel Distributed Database (SDD).

Query Period:	January 1, 2000 to October 31, 2017
Enrollment Gap:	45 Days
Age Groups:	0-4, 5-6, 7-8, 9-10, 11-12, 13-18 years
Enrollment Requirement:	183 Days
Coverage Requirement:	Medical and Drug Coverage
Results Stratified by:	Sex, Age by Sex, Year by Sex

	Event					Inclusion Criteria			
Scenario	Index Event	Care Setting	Washout (Days)	Cohort Definition	Censor at Death	Inclusion	Care Setting	Code Days	Lookback Period
7	Well visit	AV, OA	0	Retain first valid diagnosis only	Yes	---	---	---	---
8	Well visit	AV, OA	0	Retain first valid diagnosis only	Yes	Well visit	AV, OA	One or more	Entire enrollment history pre-index up to day before index date
9	Well visit	AV, OA	0	Retain first valid diagnosis only	Yes	Well visit	AV, OA	Two or more	Entire enrollment history pre-index up to day before index date

International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360.

National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."