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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 mpl1p\_wp001\_nsdv\_v01, Report 1 of 1

**Request ID:** mpl1p\_wp001\_nsdv\_v01

**Request Description:** This report contains the estimated number of new users of Sodium/Glucose Cotransporter (SGLT-2) Inhibitors, Sulfonylureas, and Dipeptidyl peptidase-4 (DPP-4) Inhibitors among all users overall, users with Type I diabetes codes, and users with Type II diabetes codes.

**Sentinel Modular Program Tool Used:** The Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.0.3, with additional custom code was used for this analysis.

**Data Source:** Data from April 1, 2013 to September 30, 2015 from 15 Data Partners contributing to the Sentinel Distributed Database (SDD) were included in this report. This request was distributed on July 11, 2017. See Appendix A for a list of the latest dates of available data for each Data Partner.

**Study Design:** This request was designed to identify exposures and follow-up time using three different types of diabetes as inclusion or exclusion criteria. See Appendix B for specific codes as defined by International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM). The number of exposure episodes, number of individuals, and days at risk in the SDD were calculated overall and were stratified by age group, sex, and year.

**Exposure of Interest:** The exposures of interest were SGLT-2 Inhibitors, Sulfonylureas, and DPP-4 Inhibitors, which were defined using National Drug Codes (NDCs). Please refer to Appendix C for specific codes and Appendix D for a list of generic and brand names.

**Cohort Eligibility Criteria:** Patients were required to be continuously enrolled in plans with both medical and drug coverage for at least one year (365 days) before their dispensing date, during which gaps in coverage of up to 45 days were allowed. Members with exposure to SGLT-2 Inhibitors, Sulfonylureas, and DPP-4 Inhibitors within one year (365 days) prior initiation of the exposure of interest were excluded. Members with gestational diabetes during the 273 days prior to initiation of the exposure of interest were excluded. The following age groups were included in the cohort: <22, 22-45, 45-65, and 65+ years.

**Follow-Up Time:** Exposure episode lengths were defined using outpatient pharmacy dispensing days supplied to create a sequence of continuous exposure. Exposure episodes were considered continuous if gaps in days supply were less than 10 days. The end date of each exposure episode was extended by 10 additional days. Follow-up began on the day on which the first exposure of interest was dispensed and continued until the first occurrence of any of the following: 1) disenrollment; 2) the study end date (September 30, 2015); 3) the end date of the data provided by each Data Partner (see Appendix A); or 4) the end of the exposure episode. Only the first valid incident exposure episode that occurred during the study period was included per patient.

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

**Limitations:** Algorithms to define exposures are imperfect and, therefore, may be misclassified.

**Notes:** Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelssystem.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.

**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). The Care Setting, 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: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes

**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 and medical coverage during the query period.

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

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

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

**Event Deduplication** - specifies how events are counted by the MP algorithm: 0: Counts all occurrences of an HOI during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the

**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. Extensions days are added after any episode gaps have been bridged

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

**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.

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

**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.

**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

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

**Treatment Episode Truncation Indicator** - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified

**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

**Table 1: Summary of Number of Sodium/Glucose Cotransporter (SGLT-2) Inhibitors, Sulfonylureas, and Dipeptidyl peptidase-4 (DPP-4) Inhibitors Users in the Sentinel Distributed Database from April 1, 2013 to September 30, 2015**

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>DPP-4 users with Type I diabetes</b>	13,942	13,942	59,269	2,243,006	2,580,270	6,555.1	610,068	621,016.4	22.85	160.88	4.25	37.84
<b>DPP-4 users with Type II diabetes</b>	162,155	162,155	717,491	27,370,328	31,636,746	79,769.7	3,968,637	4,972,073.4	40.86	168.79	4.42	38.15
<b>All DPP-4 users</b>	167,989	167,989	742,049	28,242,364	32,666,533	82,326.8	45,025,313	67,081,225.3	3.73	168.12	4.42	38.06
<b>SGLT2 users with Type I diabetes</b>	11,740	11,740	61,839	2,206,046	2,281,834	6,402.1	651,156	665,074.8	18.03	187.91	5.27	35.67
<b>SGLT2 users with Type II diabetes</b>	102,878	102,878	572,014	19,873,575	20,690,040	57,662.5	4,197,485	5,475,821.4	24.51	193.18	5.56	34.74
<b>All SGLT2 users</b>	106,080	106,080	586,863	20,359,333	21,195,127	59,092.3	45,253,247	67,601,584.8	2.34	191.92	5.53	34.69
<b>Sulfonylurea users with Type I diabetes</b>	15,583	15,583	66,469	2,925,967	4,329,053	8,429.1	543,242	556,182.8	28.69	187.77	4.27	44.02
<b>Sulfonylurea users with Type II diabetes</b>	234,371	234,371	1,044,304	46,512,472	66,107,052	133,843.1	3,568,296	4,186,701.5	65.68	198.46	4.46	44.54
<b>All sulfonylurea users</b>	256,108	256,108	1,110,397	48,904,529	69,552,821	140,999.5	44,626,402	66,261,246.9	5.74	190.95	4.34	44.04

**Table 2: Summary of Number of Sodium/Glucose Cotransporter (SGLT-2) Inhibitors, Sulfonylureas, and Dipeptidyl peptidase-4 (DPP-4) Inhibitors Users in the Sentinel Distributed Database from April 1, 2013 to September 30, 2015 by Age Group**

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>DPP-4 users with Type I diabetes</b>												
0-21 Years	61	61	192	5,971	7,129	18.3	41,675	53,373.9	1.46	97.89	3.15	31.10
22-44 Years	1,341	1,341	4,254	141,088	177,805	427.3	107,547	108,425.9	12.47	105.21	3.17	33.17
45-64 Years	6,179	6,179	25,557	949,209	1,129,378	2,785.0	238,708	224,484.9	25.89	153.62	4.14	37.14
65+ Years	6,361	6,361	29,266	1,146,738	1,265,959	3,324.6	245,113	234,731.7	25.95	180.28	4.60	39.18
<b>DPP-4 users with Type II diabetes</b>												
0-21 Years	250	250	666	21,634	27,790	65.6	54,234	43,093.3	4.61	86.54	2.66	32.48
22-44 Years	18,937	18,937	68,072	2,293,349	2,873,233	6,871.6	535,206	462,530.5	35.38	121.10	3.59	33.69
45-64 Years	85,827	85,827	395,341	14,476,608	17,195,043	42,215.7	1,891,122	2,136,896.1	45.38	168.67	4.61	36.62
65+ Years	57,141	57,141	253,412	10,578,737	11,540,681	30,616.9	1,656,123	2,329,553.4	34.50	185.13	4.43	41.75
<b>All DPP-4 users</b>												
0-21 Years	329	329	816	27,197	34,817	82.7	12,123,338	17,313,278.8	0.03	82.67	2.48	33.33
22-44 Years	20,241	20,241	72,563	2,439,716	3,054,377	7,310.5	16,053,449	20,230,121.7	1.26	120.53	3.58	33.62
45-64 Years	89,094	89,094	409,765	14,981,780	17,804,860	43,695.9	13,945,078	20,405,237.3	6.39	168.16	4.60	36.56
65+ Years	58,325	58,325	258,905	10,793,671	11,772,479	31,237.7	5,416,360	9,132,587.5	10.77	185.06	4.44	41.69
<b>SGLT2 users with Type I diabetes</b>												
0-21 Years	86	86	343	11,211	11,211	32.9	41,722	53,412.9	2.06	130.36	3.99	32.69
22-44 Years	1,972	1,972	8,946	297,889	307,402	878.9	110,386	110,664.8	17.86	151.06	4.54	33.30
45-64 Years	7,673	7,673	43,420	1,523,781	1,576,973	4,409.6	258,120	241,984.4	29.73	198.59	5.66	35.09
65+ Years	2,009	2,009	9,130	373,165	386,248	1,080.7	265,349	259,012.7	7.57	185.75	4.54	40.87
<b>SGLT2 users with Type II diabetes</b>												
0-21 Years	156	156	523	16,738	17,806	50.0	54,397	43,414.3	2.87	107.29	3.35	32.00
22-44 Years	15,210	15,210	70,851	2,305,360	2,423,877	6,820.5	556,473	498,694.2	27.33	151.57	4.66	32.54
45-64 Years	72,235	72,235	428,272	14,654,677	15,270,037	42,418.5	2,028,144	2,390,147.1	35.62	202.88	5.93	34.22
65+ Years	15,277	15,277	72,368	2,896,800	2,978,320	8,373.5	1,744,950	2,543,565.7	8.75	189.62	4.74	40.03
<b>All SGLT2 users</b>												
0-21 Years	213	213	701	22,796	24,114	68.3	12,123,509	17,313,702.7	0.02	107.02	3.29	32.52
22-44 Years	16,235	16,235	74,784	2,430,709	2,553,733	7,196.4	16,074,553	20,268,778.4	1.01	149.72	4.61	32.50
45-64 Years	74,153	74,153	438,156	14,976,652	15,605,871	43,359.1	14,081,921	20,668,676.0	5.27	201.97	5.91	34.18
65+ Years	15,479	15,479	73,222	2,929,176	3,011,409	8,468.5	5,505,061	9,350,427.7	2.81	189.24	4.73	40.00

**Table 2: Summary of Number of Sodium/Glucose Cotransporter (SGLT-2) Inhibitors, Sulfonylureas, and Dipeptidyl peptidase-4 (DPP-4) Inhibitors Users in the Sentinel Distributed Database from April 1, 2013 to September 30, 2015 by Age Group**

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Sulfonylurea users with Type I diabetes</b>												
0-21 Years	133	133	415	13,936	19,164	42.4	41,585	53,214.3	3.20	104.78	3.12	33.58
22-44 Years	1,703	1,703	5,145	179,855	279,549	543.0	104,726	106,094.2	16.26	105.61	3.02	34.96
45-64 Years	6,862	6,862	28,257	1,127,821	1,735,217	3,279.2	217,461	205,731.6	31.56	164.36	4.12	39.91
65+ Years	6,885	6,885	32,652	1,604,355	2,295,123	4,564.5	200,666	191,142.6	34.31	233.02	4.74	49.13
<b>Sulfonylurea users with Type II diabetes</b>												
0-21 Years	491	491	1,381	48,123	71,613	146.3	54,017	42,667.9	9.09	98.01	2.81	34.85
22-44 Years	29,070	29,070	100,124	3,625,358	5,422,677	10,800.7	511,309	424,721.5	56.85	124.71	3.44	36.21
45-64 Years	122,895	122,895	544,712	22,082,398	32,336,575	64,009.1	1,731,958	1,864,096.1	70.96	179.69	4.43	40.54
65+ Years	81,915	81,915	398,087	20,756,593	28,276,188	58,887.1	1,416,752	1,855,216.1	57.82	253.39	4.86	52.14
<b>All sulfonylurea users</b>												
0-21 Years	874	874	1,996	67,235	100,554	209.2	12,123,091	17,312,546.6	0.07	76.93	2.28	33.68
22-44 Years	41,191	41,191	126,773	4,459,487	6,673,891	13,421.0	16,028,456	20,175,903.1	2.57	108.26	3.08	35.18
45-64 Years	129,200	129,200	569,947	22,989,168	33,673,726	66,672.9	13,786,508	20,122,088.3	9.37	177.93	4.41	40.34
65+ Years	84,843	84,843	411,681	21,388,639	29,104,651	60,696.4	5,178,330	8,650,708.9	16.38	252.10	4.85	51.95

**Table 3: Summary of Number of Sodium/Glucose Cotransporter (SGLT-2) Inhibitors, Sulfonylureas, and Dipeptidyl peptidase-4 (DPP-4) Inhibitors Users in the Sentinel Distributed Database from April 1, 2013 to September 30, 2015 by Sex**

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>DPP-4 users with Type I diabetes</b>												
Female	6,781	6,781	28,314	1,064,453	1,206,588	3,114.5	293,715	298,620.9	23.09	156.98	4.18	37.59
Male	7,160	7,160	30,954	1,178,523	1,373,622	3,440.5	316,289	322,331.1	22.64	164.60	4.32	38.07
Unknown	1	1	1	30	60	0.1	64	64.4	15.63	30.00	1.00	30.00
<b>DPP-4 users with Type II diabetes</b>												
Female	73,497	73,497	314,931	11,917,499	13,623,245	34,810.8	1,939,400	2,425,361.2	37.90	162.15	4.28	37.84
Male	88,640	88,640	402,468	15,449,259	18,009,362	44,949.1	2,028,907	2,546,212.7	43.69	174.29	4.54	38.39
Unknown	18	18	92	3,570	4,139	9.8	330	499.5	54.55	198.33	5.11	38.80
<b>All DPP-4 users</b>												
Female	76,271	76,271	326,269	12,318,625	14,097,730	35,989.7	22,923,058	34,333,533.6	3.33	161.51	4.28	37.76
Male	91,700	91,700	415,688	15,920,169	18,564,665	46,327.3	22,100,310	32,744,573.5	4.15	173.61	4.53	38.30
Unknown	18	18	92	3,570	4,139	9.8	1,945	3,118.2	9.25	198.33	5.11	38.80
<b>SGLT2 users with Type I diabetes</b>												
Female	5,503	5,503	26,539	938,195	969,749	2,737.6	312,157	318,778.7	17.63	170.49	4.82	35.35
Male	6,235	6,235	35,264	1,266,780	1,311,014	3,661.5	338,931	346,228.8	18.40	203.17	5.66	35.92
Unknown	2	2	36	1,071	1,071	3.0	68	67.3	29.41	535.50	18.00	29.75
<b>SGLT2 users with Type II diabetes</b>												
Female	44,641	44,641	228,685	7,864,920	8,192,011	22,941.3	2,034,658	2,644,159.9	21.94	176.18	5.12	34.39
Male	58,227	58,227	343,261	12,006,447	12,495,822	34,714.9	2,162,474	2,831,097.7	26.93	206.20	5.90	34.98
Unknown	10	10	68	2,208	2,208	6.3	353	563.8	28.33	220.80	6.80	32.47
<b>All SGLT2 users</b>												
Female	46,390	46,390	236,343	8,110,963	8,445,443	23,668.8	23,018,084	34,558,871.8	2.02	174.84	5.09	34.32
Male	59,680	59,680	350,452	12,246,162	12,747,476	35,417.1	22,233,196	33,039,525.9	2.68	205.20	5.87	34.94
Unknown	10	10	68	2,208	2,208	6.3	1,967	3,187.1	5.08	220.80	6.80	32.47
<b>Sulfonylurea users with Type I diabetes</b>												
Female	7,482	7,482	31,387	1,366,965	2,005,313	3,943.3	263,377	268,859.6	28.41	182.70	4.20	43.55
Male	8,100	8,100	35,081	1,558,972	2,323,725	4,485.6	279,809	287,269.8	28.95	192.47	4.33	44.44
Unknown	1	1	1	30	15	0.1	56	53.4	17.86	30.00	1.00	30.00
<b>Sulfonylurea users with Type II diabetes</b>												
Female	104,290	104,290	450,995	20,081,589	28,324,098	57,851.7	1,764,565	2,074,973.4	59.10	192.56	4.32	44.53
Male	130,069	130,069	593,265	26,429,123	37,780,708	75,986.3	1,803,433	2,111,314.0	72.12	203.19	4.56	44.55
Unknown	12	12	44	1,760	2,245	5.1	298	414.1	40.27	146.67	3.67	40.00



**Table 3: Summary of Number of Sodium/Glucose Cotransporter (SGLT-2) Inhibitors, Sulfonylureas, and Dipeptidyl peptidase-4 (DPP-4) Inhibitors Users in the Sentinel Distributed Database from April 1, 2013 to September 30, 2015 by Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>All sulfonylurea users</b>												
Female	119,298	119,298	490,549	21,445,026	30,286,972	61,999.7	22,748,041	33,961,650.1	5.24	179.76	4.11	43.72
Male	136,797	136,797	619,803	27,457,713	39,263,574	78,994.5	21,876,449	32,296,565.9	6.25	200.72	4.53	44.30
Unknown	13	13	45	1,790	2,275	5.2	1,912	3,031.0	6.80	137.69	3.46	39.78

**Table 4: Summary of Number of Sodium/Glucose Cotransporter (SGLT-2) Inhibitors, Sulfonylureas, and Dipeptidyl peptidase-4 (DPP-4) Inhibitors Users in the Sentinel Distributed Database from April 1, 2013 to September 30, 2015 by Year**

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>DPP-4 users with Type I diabetes</b>												
2013	4,478	4,478	20,159	774,574	896,771	2,256.4	375,047	203,134.1	11.94	172.97	4.50	38.42
2014	5,391	5,391	23,115	867,961	1,004,588	2,538.6	381,469	243,930.5	14.13	161.00	4.29	37.55
2015	4,073	4,073	15,995	600,471	678,911	1,760.1	328,464	173,951.7	12.40	147.43	3.93	37.54
<b>DPP-4 users with Type II diabetes</b>												
2013	47,699	47,699	223,235	8,515,535	9,914,735	24,779.5	2,486,604	1,483,300.7	19.18	178.53	4.68	38.15
2014	63,707	63,707	282,003	10,832,267	12,583,034	31,551.6	2,644,519	1,956,753.0	24.09	170.03	4.43	38.41
2015	50,749	50,749	212,253	8,022,526	9,138,978	23,438.7	2,580,531	1,532,019.7	19.67	158.08	4.18	37.80
<b>All DPP-4 users</b>												
2013	49,441	49,441	230,852	8,782,298	10,235,620	25,559.7	31,241,829	20,599,454.2	1.58	177.63	4.67	38.04
2014	66,001	66,001	291,571	11,181,275	12,998,595	32,575.8	31,996,334	26,448,509.8	2.06	169.41	4.42	38.35
2015	52,547	52,547	219,626	8,278,791	9,432,319	24,191.4	30,674,259	20,033,261.2	1.71	157.55	4.18	37.69
<b>SGLT2 users with Type I diabetes</b>												
2013	1,764	1,764	10,830	391,983	396,574	1,130.2	406,445	221,135.6	4.34	222.21	6.14	36.19
2014	5,183	5,183	28,323	1,013,420	1,035,434	2,934.3	408,521	261,485.1	12.69	195.53	5.46	35.78
2015	4,793	4,793	22,686	800,643	849,826	2,337.6	345,603	182,454.2	13.87	167.04	4.73	35.29
<b>SGLT2 users with Type II diabetes</b>												
2013	12,690	12,690	82,160	2,862,871	2,888,340	8,263.8	2,707,320	1,657,502.2	4.69	225.60	6.47	34.85
2014	43,926	43,926	257,961	8,945,932	9,193,413	25,906.3	2,846,864	2,158,111.2	15.43	203.66	5.87	34.68
2015	46,262	46,262	231,893	8,064,772	8,608,288	23,492.4	2,759,448	1,660,208.0	16.76	174.33	5.01	34.78
<b>All SGLT2 users</b>												
2013	13,001	13,001	83,656	2,912,557	2,939,031	8,409.6	31,464,368	20,779,195.9	0.41	224.03	6.43	34.82
2014	45,211	45,211	264,104	9,149,926	9,402,240	26,504.4	32,199,994	26,656,329.0	1.40	202.38	5.84	34.65
2015	47,868	47,868	239,103	8,296,850	8,853,856	24,178.3	30,855,782	20,166,059.9	1.55	173.33	5.00	34.70
<b>Sulfonylurea users with Type I diabetes</b>												
2013	5,096	5,096	23,624	1,046,256	1,564,705	3,004.6	330,535	179,299.4	15.42	205.31	4.64	44.29
2014	6,196	6,196	26,343	1,169,745	1,733,898	3,373.2	340,229	218,954.3	18.21	188.79	4.25	44.40
2015	4,291	4,291	16,502	709,966	1,030,450	2,051.3	296,571	157,929.1	14.47	165.45	3.85	43.02
<b>Sulfonylurea users with Type II diabetes</b>												
2013	69,513	69,513	335,107	14,892,519	21,457,589	42,750.9	2,159,600	1,244,709.1	32.19	214.24	4.82	44.44
2014	93,316	93,316	423,228	18,962,732	26,976,667	54,551.4	2,321,355	1,648,558.8	40.20	203.21	4.54	44.81
2015	71,542	71,542	285,969	12,657,221	17,672,796	36,540.8	2,247,724	1,293,433.6	31.83	176.92	4.00	44.26

**Table 4: Summary of Number of Sodium/Glucose Cotransporter (SGLT-2) Inhibitors, Sulfonylureas, and Dipeptidyl peptidase-4 (DPP-4) Inhibitors Users in the Sentinel Distributed Database from April 1, 2013 to September 30, 2015 by Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>All sulfonylurea users</b>												
2013	76,202	76,202	355,337	15,633,555	22,528,923	44,967.2	30,911,164	20,351,220.0	2.47	205.16	4.66	44.00
2014	101,903	101,903	450,428	19,944,358	28,406,519	57,480.5	31,669,578	26,127,444.6	3.22	195.72	4.42	44.28
2015	78,003	78,003	304,632	13,326,616	18,617,380	38,551.8	30,333,165	19,782,582.4	2.57	170.85	3.91	43.75

**Appendix A: Latest Date of Available Data for Each Data Partner up to Request End Date (September 30, 2015)**

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<b>DP ID</b>	<b>Start Date</b>	<b>End Date</b>
DP0001	1/2/2000	5/31/2015
DP0002	1/1/2005	9/30/2015
DP0003	1/1/2008	9/30/2015
DP0004	6/1/2007	9/30/2015
DP0005	1/1/2006	9/30/2015
DP0006	1/1/2000	10/31/2014
DP0007	1/1/2000	9/30/2015
DP0008	1/1/2000	9/30/2015
DP0009	1/1/2000	9/30/2015
DP0010	1/1/2000	9/30/2015
DP0011	1/1/2000	9/30/2015
DP0012	1/1/2012	9/30/2015
DP0013	1/1/2000	9/30/2015
DP0014	1/1/2004	9/30/2015
DP0015	1/1/2008	9/30/2015

**Appendix B. List of International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM)  
Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request**

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<b>Code</b>	<b>Code Type</b>
<b>Users with Type I diabetes</b>	
250.x1	ICD-9-CM Diagnosis Code <i>or</i>
250.x3	ICD-9-CM Diagnosis Code
<b>Users with Type II diabetes</b>	
250.x2	ICD-9-CM Diagnosis Code <i>or</i>
250.x0	ICD-9-CM Diagnosis Code
<b>Gestational Diabetes</b>	
648.8	ICD-9-CM Diagnosis Code
648.8x	ICD-9-CM Diagnosis Code

**Appendix C: List of Generic Names and Brand Names used for Exposures in this Request**

Generic Name	Brand Name	Form	Route	Strength (MG)
<b>Dipeptidyl peptidase-4 (DPP-4) Inhibitors</b>				
ALOGLIPTIN BENZOATE	Nesina	tablet	oral	12.5
ALOGLIPTIN BENZOATE	Nesina	tablet	oral	25
ALOGLIPTIN BENZOATE	Nesina	tablet	oral	6.25
ALOGLIPTIN BENZOATE/METFORMIN HCL	Kazano	tablet	oral	12.5-1,000
ALOGLIPTIN BENZOATE/METFORMIN HCL	Kazano	tablet	oral	12.5-500
ALOGLIPTIN BENZOATE/PIOGLITAZONE HCL	Oseni	tablet	oral	12.5-15
ALOGLIPTIN BENZOATE/PIOGLITAZONE HCL	Oseni	tablet	oral	12.5-30
ALOGLIPTIN BENZOATE/PIOGLITAZONE HCL	Oseni	tablet	oral	12.5-45
ALOGLIPTIN BENZOATE/PIOGLITAZONE HCL	Oseni	tablet	oral	25-15
ALOGLIPTIN BENZOATE/PIOGLITAZONE HCL	Oseni	tablet	oral	25-45
EMPAGLIFLOZIN/LINAGLIPTIN	Glyxambi	tablet	oral	10-5
EMPAGLIFLOZIN/LINAGLIPTIN	Glyxambi	tablet	oral	25-5
LINAGLIPTIN	Tradjenta	tablet	oral	5
LINAGLIPTIN/METFORMIN HCL	Jentadueto	tablet	oral	2.5-1,000
LINAGLIPTIN/METFORMIN HCL	Jentadueto	tablet	oral	2.5-500
LINAGLIPTIN/METFORMIN HCL	Jentadueto	tablet	oral	2.5-850
SAXAGLIPTIN HCL	Onglyza	tablet	oral	2.5
SAXAGLIPTIN HCL	Onglyza	tablet	oral	5
SAXAGLIPTIN HCL/METFORMIN HCL	Kombiglyze XR	tablet, ER multiphase 24 hr	oral	2.5-1,000
SAXAGLIPTIN HCL/METFORMIN HCL	Kombiglyze XR	tablet, ER multiphase 24 hr	oral	5-1,000
SAXAGLIPTIN HCL/METFORMIN HCL	Kombiglyze XR	tablet, ER multiphase 24 hr	oral	2.5-1,000
SAXAGLIPTIN HCL/METFORMIN HCL	Kombiglyze XR	tablet, ER multiphase 24 hr	oral	5-500
SITAGLIPTIN PHOSPHATE	Januvia	tablet	oral	100
SITAGLIPTIN PHOSPHATE	Januvia	tablet	oral	25
SITAGLIPTIN PHOSPHATE	Januvia	tablet	oral	50
SITAGLIPTIN PHOSPHATE/METFORMIN HCL	Janumet XR	tablet, ER multiphase 24 hr	oral	50-500
SITAGLIPTIN PHOSPHATE/METFORMIN HCL	Janumet XR	tablet, ER multiphase 24 hr	oral	50-1,000
SITAGLIPTIN PHOSPHATE/METFORMIN HCL	Janumet XR	tablet, ER multiphase 24 hr	oral	100-1,000
SITAGLIPTIN PHOSPHATE/METFORMIN HCL	Janumet	tablet	oral	50-1,000

**Appendix C: List of Generic Names and Brand Names used for Exposures in this Request**

Generic Name	Brand Name	Form	Route	Strength (MG)
SITAGLIPTIN PHOSPHATE/METFORMIN HCL	Janumet	tablet	oral	50-500
SITAGLIPTIN PHOSPHATE/SIMVASTATIN	Juvisync	tablet	oral	50-10
SITAGLIPTIN PHOSPHATE/SIMVASTATIN	Juvisync	tablet	oral	50-20
SITAGLIPTIN PHOSPHATE/SIMVASTATIN	Juvisync	tablet	oral	50-40
SITAGLIPTIN PHOSPHATE/SIMVASTATIN	Juvisync	tablet	oral	100-10
SITAGLIPTIN PHOSPHATE/SIMVASTATIN	Juvisync	tablet	oral	100-20
SITAGLIPTIN PHOSPHATE/SIMVASTATIN	Juvisync	tablet	oral	100-40
<b>Sodium/Glucose Cotransporter (SGLT-2) Inhibitors</b>				
CANAGLIFLOZIN	Invokana	tablet	oral	100
CANAGLIFLOZIN	Invokana	tablet	oral	300
CANAGLIFLOZIN/METFORMIN HCL	Invokamet	tablet	oral	50-500
CANAGLIFLOZIN/METFORMIN HCL	Invokamet	tablet	oral	50-1,000
CANAGLIFLOZIN/METFORMIN HCL	Invokamet	tablet	oral	150-500
CANAGLIFLOZIN/METFORMIN HCL	Invokamet	tablet	oral	150-1,000
DAPAGLIFLOZIN PROPANEDIOL	Farxiga	tablet	oral	5
DAPAGLIFLOZIN PROPANEDIOL	Farxiga	tablet	oral	10
DAPAGLIFLOZIN PROPANEDIOL/METFORMIN HC Xigduo XR		tablet, IR & ER, biphasic 24hr	oral	5-500
DAPAGLIFLOZIN PROPANEDIOL/METFORMIN HC Xigduo XR		tablet, IR & ER, biphasic 24hr	oral	5-1,000
DAPAGLIFLOZIN PROPANEDIOL/METFORMIN HC Xigduo XR		tablet, IR & ER, biphasic 24hr	oral	10-500
DAPAGLIFLOZIN PROPANEDIOL/METFORMIN HC Xigduo XR		tablet, IR & ER, biphasic 24hr	oral	10-1,000
EMPAGLIFLOZIN	Jardiance	tablet	oral	10
EMPAGLIFLOZIN	Jardiance	tablet	oral	25
EMPAGLIFLOZIN/LINAGLIPTIN	Glyxambi	tablet	oral	25-5
EMPAGLIFLOZIN/LINAGLIPTIN	Glyxambi	tablet	oral	10-5
<b>Sulfonylureas</b>				
CHLORPROPAMIDE	chlorpropamide	tablet	oral	100
CHLORPROPAMIDE	chlorpropamide	tablet	oral	250
GLIMEPIRIDE	Amaryl	tablet	oral	1

**Appendix C: List of Generic Names and Brand Names used for Exposures in this Request**

Generic Name	Brand Name	Form	Route	Strength (MG)
GLIMEPIRIDE	Amaryl	tablet	oral	2
GLIMEPIRIDE	Amaryl	tablet	oral	4
GLIMEPIRIDE	glimepiride	tablet	oral	1
GLIMEPIRIDE	glimepiride	tablet	oral	2
GLIMEPIRIDE	glimepiride	tablet	oral	4
GLIPIZIDE	Glucotrol XL	tablet extended release 24hr	oral	2.5
GLIPIZIDE	Glucotrol XL	tablet extended release 24hr	oral	5
GLIPIZIDE	Glucotrol XL	tablet extended release 24hr	oral	10
GLIPIZIDE	Glucotrol	tablet	oral	5
GLIPIZIDE	Glucotrol	tablet	oral	10
GLIPIZIDE	glipizide	tablet	oral	5
GLIPIZIDE	glipizide	tablet	oral	10
GLIPIZIDE	glipizide	tablet extended release 24hr	oral	2.5
GLIPIZIDE	glipizide	tablet extended release 24hr	oral	5
GLIPIZIDE	glipizide	tablet extended release 24hr	oral	10
GLIPIZIDE/METFORMIN HCL	Metaglip	tablet	oral	2.5-500
GLIPIZIDE/METFORMIN HCL	Metaglip	tablet	oral	5-500
GLIPIZIDE/METFORMIN HCL	glipizide-metformin	tablet	oral	2.5-250
GLIPIZIDE/METFORMIN HCL	glipizide-metformin	tablet	oral	2.5-500
GLIPIZIDE/METFORMIN HCL	glipizide-metformin	tablet	oral	5-500
GLYBURIDE	Diabeta	tablet	oral	2.5
GLYBURIDE	Diabeta	tablet	oral	5
GLYBURIDE	Diabeta	tablet	oral	1.25
GLYBURIDE	glyburide	tablet	oral	1.25
GLYBURIDE	glyburide	tablet	oral	2.5
GLYBURIDE	glyburide	tablet	oral	5
GLYBURIDE	Diabeta	tablet	oral	2.5
GLYBURIDE	Diabeta	tablet	oral	5
GLYBURIDE,MICRONIZED	Glynase	tablet	oral	1.5
GLYBURIDE,MICRONIZED	Glynase	tablet	oral	3



**Appendix C: List of Generic Names and Brand Names used for Exposures in this Request**

Generic Name	Brand Name	Form	Route	Strength (MG)
GLYBURIDE,MICRONIZED	Glynase	tablet	oral	6
GLYBURIDE,MICRONIZED	glyburide micronized	tablet	oral	1.5
GLYBURIDE,MICRONIZED	glyburide micronized	tablet	oral	3
GLYBURIDE,MICRONIZED	glyburide micronized	tablet	oral	6
GLYBURIDE/METFORMIN HCL	Glucovance	tablet	oral	2.5-500
GLYBURIDE/METFORMIN HCL	Glucovance	tablet	oral	5-500
GLYBURIDE/METFORMIN HCL	glyburide-metformin	tablet	oral	1.25-250
GLYBURIDE/METFORMIN HCL	glyburide-metformin	tablet	oral	2.5-500
GLYBURIDE/METFORMIN HCL	glyburide-metformin	tablet	oral	5-500
PIOGLITAZONE HCL/GLIMEPIRIDE	pioglitazone-glimepiride	tablet	oral	30-2
PIOGLITAZONE HCL/GLIMEPIRIDE	pioglitazone-glimepiride	tablet	oral	30-4
PIOGLITAZONE HCL/GLIMEPIRIDE	DUETACT	tablet	oral	30-2
PIOGLITAZONE HCL/GLIMEPIRIDE	DUETACT	tablet	oral	30-4
PIOGLITAZONE HCL/GLIMEPIRIDE	pioglitazone-glimepiride	tablet	oral	30-2
PIOGLITAZONE HCL/GLIMEPIRIDE	pioglitazone-glimepiride	tablet	oral	30-4
ROSIGLITAZONE MALEATE/GLIMEPIRIDE	Avandaryl	tablet	oral	8-2
ROSIGLITAZONE MALEATE/GLIMEPIRIDE	Avandaryl	tablet	oral	8-4
ROSIGLITAZONE MALEATE/GLIMEPIRIDE	Avandaryl	tablet	oral	4-1
ROSIGLITAZONE MALEATE/GLIMEPIRIDE	Avandaryl	tablet	oral	4-2
ROSIGLITAZONE MALEATE/GLIMEPIRIDE	Avandaryl	tablet	oral	4-4
TOLAZAMIDE	tolazamide	tablet	oral	250
TOLAZAMIDE	tolazamide	tablet	oral	500
TOLBUTAMIDE	tolbutamide	tablet	oral	500

**Appendix D: List of Generic Names and Brand Names used for Exposures in this Request**

Generic Name	Brand Name
<b>Dipeptidyl peptidase-4 (DPP-4) Inhibitors</b>	
SITAGLIPTIN PHOSPHATE/METFORMIN HCL	Janumet XR
SITAGLIPTIN PHOSPHATE	Januvia
SITAGLIPTIN PHOSPHATE/SIMVASTATIN	Juvisync
SITAGLIPTIN PHOSPHATE/METFORMIN HCL	Janumet
SAXAGLIPTIN HCL	Onglyza
SAXAGLIPTIN HCL/METFORMIN HCL	Kombiglyze XR
EMPAGLIFLOZIN/LINAGLIPTIN	Glyxambi
LINAGLIPTIN/METFORMIN HCL	Jentadueto
ALOGLIPTIN BENZOATE/METFORMIN HCL	Kazano
ALOGLIPTIN BENZOATE	Nesina
ALOGLIPTIN BENZOATE/PIOGLITAZONE HCL	Oseni
LINAGLIPTIN	Tradjenta
<b>Sodium/Glucose Cotransporter (SGLT-2) Inhibitors</b>	
CANAGLIFLOZIN	Invokana
CANAGLIFLOZIN/METFORMIN HCL	Invokamet
DAPAGLIFLOZIN PROPANEDIOL	Farxiga
DAPAGLIFLOZIN PROPANEDIOL/METFORMIN HCL	Xigduo XR
EMPAGLIFLOZIN/LINAGLIPTIN	Glyxambi
EMPAGLIFLOZIN	Jardiance
<b>Sulfonylureas</b>	
ROSIGLITAZONE MALEATE/GLIMEPIRIDE	Avandaryl
GLYBURIDE, MICRONIZED	Glynase
GLYBURIDE	Diabeta
GLIMEPIRIDE	Amaryl
GLIPIZIDE	Glucotrol XL
GLIPIZIDE	Glucotrol
GLYBURIDE/METFORMIN HCL	Glucovance

**Appendix D: List of Generic Names and Brand Names used for Exposures in this Request**

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<b>Generic Name</b>	<b>Brand Name</b>
GLIPIZIDE/METFORMIN HCL	Metaglip
GLIMEPIRIDE	Glimepiride
GLYBURIDE/METFORMIN HCL	Glyburide-metformin
GLYBURIDE, MICRONIZED	Glyburide micronized
GLYBURIDE	Glyburide
GLIPIZIDE	Glipizide
CHLORPROPAMIDE	Chlorpropamide
TOLBUTAMIDE	Tolbutamide
TOLAZAMIDE	Tolazamide
GLIPIZIDE/METFORMIN HCL	Glipizide-metformin
PIOGLITAZONE HCL/GLIMEPIRIDE	Pioglitazone-glimepiride
PIOGLITAZONE HCL/GLIMEPIRIDE	Duetact

**Appendix E: Specifications of Parameters Used in the Analyses for this Request**

FDA has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.0.3, to investigate the number of Sodium/Glucose Cotransporter (SGLT-2) Inhibitor, Sulfonylurea, and Dipeptidyl peptidase-4 (DPP-4) Inhibitor users overall as well as those with Type I diabetes or Type II diabetes. In addition, Rapid Analytic Development and Response (RaDaR) code was requested to investigate the proportion of users with Type II diabetes codes from these user populations.

**Age Groups:** 0-21; 22-44; 45-64; 65+  
**Query Period:** April 1, 2013 - September 30, 2015      Freeze Data= Y  
**Coverage Requirement:** Medical and Drug Coverage  
**Enrollment Gap:** 45 days

Drug/Exposure										Inclusion/Exclusion			Outcome			
Enrollment Requirement	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap	Episode Extension Period	Minimum Episode Duration	Minimum Days Supply	Censor at Evidence of Death	Inclusion/Exclusion Criteria*	Lookback start	Lookback end	Care Setting/ PDX	Event	Caresetting	Washout