

Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-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 Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-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 the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-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 to16_cap_mpl1r_wp041

Request ID: to16_cap_mpl1r_wp041_nsdp_v01

Request Description: In this report we estimated rate of diabetic ketoacidosis (DKA) among new users of Sodium-Glucose Cotransporter-2 (SGLT-2) inhibitors, sulfonylureas, saxagliptin, and sitagliptin in the Mini-Sentinel Distributed Database (MSDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 2.0.5

Data Source: We distributed this request to 13 Data Partners on June 26, 2015. The study period included data from April 1, 2013 to March 31, 2015. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: We designed this request to identify the total number of incident users of SGLT-2 inhibitors, sulfonylureas, saxagliptin, and sitagliptin. Additionally, we calculated the total number of exposure episodes, events, and days at-risk among incident users of SGLT-2 inhibitors, sulfonylureas, saxagliptin, and sitagliptin. Data were further stratified by age, sex, and year. This is a Type 2 analysis in the Query Request Package (QRP) documentation.

Exposures of Interest: We defined the exposures of interest, new use of SGLT-2 inhibitors (specifically canagliflozin and dapagliflozin), sulfonylureas, saxagliptin, and sitagliptin, using National Drug Codes (NDCs). We defined new use as no evidence of exposure to either (a) the specific exposure of interest, or (b) any of the exposures of interest in the 183 days prior to the first qualifying (index) dispensing date. See Appendix B for generic and brand names of medical products used to define exposures in this request.

Cohort Eligibility Criteria: We required members included in the cohort to be continuously enrolled in health plans with both medical and drug coverage for at least 183 days prior to their index date, during which gaps in coverage of up to 45 days were allowed. Cohort re-entry was not allowed; users could only contribute one episode during the study period. We included the following age groups in the cohort: 0-21, 22-44, 45-64, and 65+ years.

Outcome of Interest: The outcome of interest in this request was diabetic ketoacidosis (DKA). We defined DKA using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes during an inpatient encounter. Three outcome definitions for DKA were used. Please see Appendix C for a list of ICD-9-CM diagnosis codes used to define outcome definitions in this request.

Follow-Up Time: Follow-up began on the day of the index dispensing and continued until the outcome occurred or the first occurrence of any of the following censoring events: 1) disenrollment; 2) cessation of study drug use (defined as when the day supply was exhausted for longer than 10 days without a subsequent dispensing); or 3) end of the query period (June 16, 2015). We created exposure episodes based on the number of days supplied per drug dispensing in the outpatient pharmacy dispensing data. We bridged together episodes less than 10 days apart and added 10 days to the end of each episode. These "as treated" episodes are the time during which we assessed for outcomes.

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

Limitations: Algorithms used to define exposures and outcomes are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitations in mind.

Notes: Please contact the Mini-Sentinel Operations Center (info@mini-sentinel.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (<https://dev.sentinelssystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse>).

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

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 (PDX), 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.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

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 during the query period until an event occurs.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

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.

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 Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (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 same day (e.g., de-duplicates at the group level).

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 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 dispensing).

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 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.

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.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

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

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 1a. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of the Exposure Drug Class of Interest, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹

Event Definition	New Users	New Episodes	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk	
SGLT-2 Inhibitors														
Definition 1	39,624	39,624	118,009	3,629,115	3,652,751	10,686.3	58	45,775,406	45,441,926.2	0.87	91.59	2.98	30.75	54.28
Definition 2	39,624	39,624	118,009	3,629,115	3,652,751	10,688.0	49	45,775,406	45,441,926.2	0.87	91.59	2.98	30.75	45.85
Definition 3	39,624	39,624	118,009	3,629,115	3,652,751	10,688.6	37	45,775,406	45,441,926.2	0.87	91.59	2.98	30.75	34.62
Sulfonylurea														
Definition 1	227,602	227,602	564,756	25,518,393	38,859,190	74,460.9	211	45,130,520	44,521,492.4	5.04	112.12	2.48	45.18	28.34
Definition 2	227,602	227,602	564,756	25,518,393	38,859,190	74,463.1	195	45,130,520	44,521,492.4	5.04	112.12	2.48	45.18	26.19
Definition 3	227,602	227,602	564,756	25,518,393	38,859,190	74,492.6	71	45,130,520	44,521,492.4	5.04	112.12	2.48	45.18	9.53
Saxagliptin or Sitagliptin														
Definition 1	93,142	93,142	246,625	8,792,967	10,463,040	26,142.1	77	45,581,279	45,184,591.0	2.04	94.40	2.65	35.65	29.45
Definition 2	93,142	93,142	246,625	8,792,967	10,463,040	26,143.3	71	45,581,279	45,184,591.0	2.04	94.40	2.65	35.65	27.16
Definition 3	93,142	93,142	246,625	8,792,967	10,463,040	26,149.0	37	45,581,279	45,184,591.0	2.04	94.40	2.65	35.65	14.15

¹Refer to Appendix B for a list of event definitions.

Table 1b. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of Any Exposure Drug Class, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹

Event Definition	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
SGLT-2 Inhibitors														
Definition 1	17,492	17,492	49,092	1,485,499	1,494,499	4,390.9	35	44,992,530	44,368,317.7	0.39	84.92	2.81	30.26	79.71
Definition 2	17,492	17,492	49,092	1,485,499	1,494,499	4,392.4	27	44,992,530	44,368,317.7	0.39	84.92	2.81	30.26	61.47
Definition 3	17,492	17,492	49,092	1,485,499	1,494,499	4,392.0	25	44,992,530	44,368,317.7	0.39	84.92	2.81	30.26	56.92
Definition 1 (No Truncation on Incident Exposure)	17,492	17,492	50,082	1,522,919	1,532,834	4,503.5	35	44,992,530	44,368,317.7	0.39	87.06	2.86	30.41	77.72
Sulfonylurea														
Definition 1	201,413	201,413	482,322	22,292,968	34,022,546	65,031.8	190	44,992,528	44,358,676.5	4.48	110.68	2.39	46.22	29.22
Definition 2	201,413	201,413	482,322	22,292,968	34,022,546	65,033.7	175	44,992,528	44,358,676.5	4.48	110.68	2.39	46.22	26.91
Definition 3	201,413	201,413	482,322	22,292,968	34,022,546	65,061.4	62	44,992,528	44,358,676.5	4.48	110.68	2.39	46.22	9.53
Definition 1 (No Truncation on Incident Exposure)	201,413	201,413	489,304	22,636,404	34,610,675	66,042.7	192	44,992,528	44,358,676.5	4.48	112.39	2.43	46.26	29.07
Saxagliptin or Sitagliptin														
Definition 1	54,837	54,837	139,113	4,780,323	5,834,869	14,259.2	49	44,992,530	44,366,655.4	1.22	87.17	2.54	34.36	34.36
Definition 2	54,837	54,837	139,113	4,780,323	5,834,869	14,259.7	47	44,992,530	44,366,655.4	1.22	87.17	2.54	34.36	32.96
Definition 3	54,837	54,837	139,113	4,780,323	5,834,869	14,263.5	21	44,992,530	44,366,655.4	1.22	87.17	2.54	34.36	14.72
Definition 1 (No Truncation on Incident Exposure)	54,837	54,837	144,837	5,040,596	6,160,230	15,038.2	51	44,992,530	44,366,655.4	1.22	91.92	2.64	34.80	33.91

¹Refer to Appendix B for a list of event definitions.

Table 2a. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of the Exposure Drug Class of Interest, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Age Group

Age Group (years)	New Users	New Episodes	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk	
SGLT-2 Inhibitors														
Event Definition 1														
0-21	64	64	154	4,852	4,854	14.7	1	11,830,719	11,364,868.4	0.01	75.81	2.41	31.51	681.56
22-44	6,318	6,318	16,822	492,831	495,774	1,478.9	18	16,117,120	14,269,266.6	0.39	78.00	2.66	29.30	121.71
45-64	28,544	28,544	88,554	2,709,301	2,726,886	7,959.2	34	13,787,994	13,653,855.2	2.07	94.92	3.10	30.59	42.72
65+	4,698	4,698	12,479	422,131	425,237	1,233.5	5	5,743,503	6,153,936.0	0.82	89.85	2.66	33.83	40.53
Event Definition 2														
0-21	64	64	154	4,852	4,854	14.7	1	11,830,719	11,364,868.4	0.01	75.81	2.41	31.51	681.56
22-44	6,318	6,318	16,822	492,831	495,774	1,479.5	14	16,117,120	14,269,266.6	0.39	78.00	2.66	29.30	94.62
45-64	28,544	28,544	88,554	2,709,301	2,726,886	7,960.1	30	13,787,994	13,653,855.2	2.07	94.92	3.10	30.59	37.69
65+	4,698	4,698	12,479	422,131	425,237	1,233.6	4	5,743,503	6,153,936.0	0.82	89.85	2.66	33.83	32.42
Event Definition 3														
0-21	64	64	154	4,852	4,854	14.8	0	11,830,719	11,364,868.4	0.01	75.81	2.41	31.51	0.00
22-44	6,318	6,318	16,822	492,831	495,774	1,479.0	17	16,117,120	14,269,266.6	0.39	78.00	2.66	29.30	114.94
45-64	28,544	28,544	88,554	2,709,301	2,726,886	7,960.8	18	13,787,994	13,653,855.2	2.07	94.92	3.10	30.59	22.61
65+	4,698	4,698	12,479	422,131	425,237	1,234.0	2	5,743,503	6,153,936.0	0.82	89.85	2.66	33.83	16.21
Sulfonylurea														
Event Definition 1														
0-21	499	499	876	37,714	61,757	114.7	2	11,830,450	11,364,324.3	0.04	75.58	1.76	43.05	174.29
22-44	37,314	37,314	79,342	3,234,628	5,048,442	9,713.0	32	16,075,496	14,203,222.3	2.32	86.69	2.13	40.77	32.95
45-64	114,755	114,755	292,366	12,504,710	19,702,135	36,653.6	98	13,496,922	13,259,975.7	8.50	108.97	2.55	42.77	26.74
65+	75,034	75,034	192,172	9,741,341	14,046,857	27,979.5	79	5,400,826	5,693,970.2	13.89	129.83	2.56	50.69	28.23
Event Definition 2														
0-21	499	499	876	37,714	61,757	114.9	1	11,830,450	11,364,324.3	0.04	75.58	1.76	43.05	87.07
22-44	37,314	37,314	79,342	3,234,628	5,048,442	9,713.6	28	16,075,496	14,203,222.3	2.32	86.69	2.13	40.77	28.83
45-64	114,755	114,755	292,366	12,504,710	19,702,135	36,653.9	95	13,496,922	13,259,975.7	8.50	108.97	2.55	42.77	25.92
65+	75,034	75,034	192,172	9,741,341	14,046,857	27,980.7	71	5,400,826	5,693,970.2	13.89	129.83	2.56	50.69	25.37
Event Definition 3														
0-21	499	499	876	37,714	61,757	115.1	1	11,830,450	11,364,324.3	0.04	75.58	1.76	43.05	86.90
22-44	37,314	37,314	79,342	3,234,628	5,048,442	9,716.5	14	16,075,496	14,203,222.3	2.32	86.69	2.13	40.77	14.41
45-64	114,755	114,755	292,366	12,504,710	19,702,135	36,669.7	30	13,496,922	13,259,975.7	8.50	108.97	2.55	42.77	8.18
65+	75,034	75,034	192,172	9,741,341	14,046,857	27,991.3	26	5,400,826	5,693,970.2	13.89	129.83	2.56	50.69	9.29

Table 2a. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of the Exposure Drug Class of Interest, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Age Group

Age Group (years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
Saxagliptin or Sitagliptin														
Event Definition 1														
0-21	153	153	279	9,096	11,817	28.4	0	11,830,610	11,364,710.9	0.01	59.45	1.82	32.60	0.00
22-44	11,701	11,701	27,690	887,904	1,142,231	2,721.7	13	16,100,964	14,248,757.1	0.73	75.88	2.37	32.07	47.76
45-64	49,815	49,815	134,275	4,612,923	5,656,390	13,757.5	38	13,676,666	13,517,129.2	3.64	92.60	2.70	34.35	27.62
65+	31,473	31,473	84,381	3,283,044	3,652,602	9,634.5	26	5,667,603	6,053,993.8	5.55	104.31	2.68	38.91	26.99
Event Definition 2														
0-21	153	153	279	9,096	11,817	28.4	0	11,830,610	11,364,710.9	0.01	59.45	1.82	32.60	0.00
22-44	11,701	11,701	27,690	887,904	1,142,231	2,721.7	13	16,100,964	14,248,757.1	0.73	75.88	2.37	32.07	47.76
45-64	49,815	49,815	134,275	4,612,923	5,656,390	13,757.5	38	13,676,666	13,517,129.2	3.64	92.60	2.70	34.35	27.62
65+	31,473	31,473	84,381	3,283,044	3,652,602	9,635.7	20	5,667,603	6,053,993.8	5.55	104.31	2.68	38.91	20.76
Event Definition 3														
0-21	153	153	279	9,096	11,817	28.4	0	11,830,610	11,364,710.9	0.01	59.45	1.82	32.60	0.00
22-44	11,701	11,701	27,690	887,904	1,142,231	2,722.7	9	16,100,964	14,248,757.1	0.73	75.88	2.37	32.07	33.06
45-64	49,815	49,815	134,275	4,612,923	5,656,390	13,761.7	14	13,676,666	13,517,129.2	3.64	92.60	2.70	34.35	10.17
65+	31,473	31,473	84,381	3,283,044	3,652,602	9,636.2	14	5,667,603	6,053,993.8	5.55	104.31	2.68	38.91	14.53

¹Refer to Appendix B for a list of event definitions.

Table 2b. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of Any Exposure Drug Class, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Age Group

Age Group (years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
SGLT-2 Inhibitors														
Event Definition 1														
0-21	50	50	123	3,757	3,757	11.3	1	11,830,346	11,364,190.1	0.00	75.14	2.46	30.54	886.74
22-44	3,263	3,263	8,108	237,394	238,105	713.5	15	16,062,087	14,189,614.5	0.20	72.75	2.48	29.28	210.24
45-64	12,436	12,436	36,402	1,097,127	1,104,368	3,234.2	17	13,415,379	13,170,460.3	0.93	88.22	2.93	30.14	52.56
65+	1,743	1,743	4,459	147,221	148,269	432.0	2	5,352,929	5,644,052.8	0.33	84.46	2.56	33.02	46.30
Event Definition 2														
0-21	50	50	123	3,757	3,757	11.3	1	11,830,346	11,364,190.1	0.00	75.14	2.46	30.54	886.74
22-44	3,263	3,263	8,108	237,394	238,105	714.1	11	16,062,087	14,189,614.5	0.20	72.75	2.48	29.28	154.04
45-64	12,436	12,436	36,402	1,097,127	1,104,368	3,235.1	14	13,415,379	13,170,460.3	0.93	88.22	2.93	30.14	43.28
65+	1,743	1,743	4,459	147,221	148,269	432.0	1	5,352,929	5,644,052.8	0.33	84.46	2.56	33.02	23.15
Event Definition 3														
0-21	50	50	123	3,757	3,757	11.4	0	11,830,346	11,364,190.1	0.00	75.14	2.46	30.54	0.00
22-44	3,263	3,263	8,108	237,394	238,105	713.5	15	16,062,087	14,189,614.5	0.20	72.75	2.48	29.28	210.24
45-64	12,436	12,436	36,402	1,097,127	1,104,368	3,235.2	8	13,415,379	13,170,460.3	0.93	88.22	2.93	30.14	24.73
65+	1,743	1,743	4,459	147,221	148,269	432.0	2	5,352,929	5,644,052.8	0.33	84.46	2.56	33.02	46.30
Event Definition 1 (No Truncation on Incident Exposure)														
0-21	50	50	123	3,771	3,771	11.3	1	11,830,346	11,364,190.1	0.00	75.42	2.46	30.66	883.74
22-44	3,263	3,263	8,255	242,703	243,629	729.8	15	16,062,087	14,189,614.5	0.20	74.38	2.53	29.40	205.54
45-64	12,436	12,436	37,156	1,125,886	1,133,498	3,320.4	17	13,415,379	13,170,460.3	0.93	90.53	2.99	30.30	51.20
65+	1,743	1,743	4,548	150,559	151,937	442.1	2	5,352,929	5,644,052.8	0.33	86.38	2.61	33.10	45.24
Sulfonylurea														
Event Definition 1														
0-21	478	478	822	35,468	57,625	107.9	2	11,830,346	11,364,160.8	0.04	74.20	1.72	43.15	185.31
22-44	34,262	34,262	70,471	2,927,617	4,583,498	8,786.4	30	16,062,051	14,186,874.4	2.13	85.45	2.06	41.54	34.14
45-64	99,643	99,643	243,818	10,714,326	16,987,857	31,386.6	87	13,414,875	13,166,205.6	7.43	107.53	2.45	43.94	27.72
65+	67,030	67,030	167,211	8,615,557	12,393,566	24,750.8	71	5,352,366	5,641,435.6	12.52	128.53	2.49	51.53	28.69
Event Definition 2														
0-21	478	478	822	35,468	57,625	108.0	1	11,830,346	11,364,160.8	0.04	74.20	1.72	43.15	92.57
22-44	34,262	34,262	70,471	2,927,617	4,583,498	8,787.0	26	16,062,051	14,186,874.4	2.13	85.45	2.06	41.54	29.59
45-64	99,643	99,643	243,818	10,714,326	16,987,857	31,386.9	84	13,414,875	13,166,205.6	7.43	107.53	2.45	43.94	26.76
65+	67,030	67,030	167,211	8,615,557	12,393,566	24,751.7	64	5,352,366	5,641,435.6	12.52	128.53	2.49	51.53	25.86

Table 2b. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of Any Exposure Drug Class, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Age Group

Age Group (years)	New Users	New Episodes	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk	
Event Definition 3														
0-21	478	478	822	35,468	57,625	108.3	1	11,830,346	11,364,160.8	0.04	74.20	1.72	43.15	92.38
22-44	34,262	34,262	70,471	2,927,617	4,583,498	8,789.9	12	16,062,051	14,186,874.4	2.13	85.45	2.06	41.54	13.65
45-64	99,643	99,643	243,818	10,714,326	16,987,857	31,401.1	26	13,414,875	13,166,205.6	7.43	107.53	2.45	43.94	8.28
65+	67,030	67,030	167,211	8,615,557	12,393,566	24,762.1	23	5,352,366	5,641,435.6	12.52	128.53	2.49	51.53	9.29
Event Definition 1 (No Truncation on Incident Exposure)														
0-21	478	478	833	36,235	59,902	110.2	2	11,830,346	11,364,160.8	0.04	75.81	1.74	43.50	181.53
22-44	34,262	34,262	71,422	2,969,855	4,652,983	8,914.2	30	16,062,051	14,186,874.4	2.13	86.68	2.08	41.58	33.65
45-64	99,643	99,643	248,031	10,909,168	17,328,850	31,966.0	88	13,414,875	13,166,205.6	7.43	109.48	2.49	43.98	27.53
65+	67,030	67,030	169,018	8,721,146	12,568,940	25,052.3	72	5,352,366	5,641,435.6	12.52	130.11	2.52	51.60	28.74
Saxagliptin or Sitagliptin														
Event Definition 1														
0-21	116	116	205	6,690	8,469	21.0	0	11,830,346	11,364,183.9	0.01	57.67	1.77	32.63	0.00
22-44	8,200	8,200	18,847	588,915	768,474	1,808.7	10	16,062,082	14,189,344.9	0.51	71.82	2.30	31.25	55.29
45-64	30,970	30,970	79,683	2,672,163	3,347,502	7,985.2	26	13,415,264	13,169,578.1	2.31	86.28	2.57	33.53	32.56
65+	15,551	15,551	40,378	1,512,555	1,710,424	4,444.3	13	5,352,831	5,643,548.4	2.91	97.26	2.60	37.46	29.25
Event Definition 2														
0-21	116	116	205	6,690	8,469	21.0	0	11,830,346	11,364,183.9	0.01	57.67	1.77	32.63	0.00
22-44	8,200	8,200	18,847	588,915	768,474	1,808.7	10	16,062,082	14,189,344.9	0.51	71.82	2.30	31.25	55.29
45-64	30,970	30,970	79,683	2,672,163	3,347,502	7,985.2	26	13,415,264	13,169,578.1	2.31	86.28	2.57	33.53	32.56
65+	15,551	15,551	40,378	1,512,555	1,710,424	4,444.8	11	5,352,831	5,643,548.4	2.91	97.26	2.60	37.46	24.75
Event Definition 3														
0-21	116	116	205	6,690	8,469	21.0	0	11,830,346	11,364,183.9	0.01	57.67	1.77	32.63	0.00
22-44	8,200	8,200	18,847	588,915	768,474	1,809.2	6	16,062,082	14,189,344.9	0.51	71.82	2.30	31.25	33.16
45-64	30,970	30,970	79,683	2,672,163	3,347,502	7,988.4	7	13,415,264	13,169,578.1	2.31	86.28	2.57	33.53	8.76
65+	15,551	15,551	40,378	1,512,555	1,710,424	4,444.8	8	5,352,831	5,643,548.4	2.91	97.26	2.60	37.46	18.00
Event Definition 1 (No Truncation on Incident Exposure)														
0-21	116	116	212	6,930	8,779	21.7	0	11,830,346	11,364,183.9	0.01	59.74	1.83	32.69	0.00
22-44	8,200	8,200	19,602	621,645	811,858	1,908.4	10	16,062,082	14,189,344.9	0.51	75.81	2.39	31.71	52.40
45-64	30,970	30,970	83,353	2,831,105	3,552,416	8,459.6	28	13,415,264	13,169,578.1	2.31	91.41	2.69	33.97	33.10
65+	15,551	15,551	41,670	1,580,916	1,787,178	4,648.4	13	5,352,831	5,643,548.4	2.91	101.66	2.68	37.94	27.97

¹Refer to Appendix B for a list of event definitions.

Table 3a. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of the Exposure Drug Class of Interest, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Sex

Sex	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
SGLT-2 Inhibitors														
Event Definition 1														
Female	17,028	17,028	47,939	1,450,278	1,460,208	4,296.2	33	23,262,445	23,186,623.9	0.73	85.17	2.82	30.25	76.81
Male	22,593	22,593	70,066	2,178,607	2,192,313	6,389.4	25	22,511,332	22,253,849.4	1.00	96.43	3.10	31.09	39.13
Unknown	3	3	4	230	230	0.7	0	1,629	1,452.9	1.84	76.67	1.33	57.50	0.00
Event Definition 2														
Female	17,028	17,028	47,939	1,450,278	1,460,208	4,297.7	26	23,262,445	23,186,623.9	0.73	85.17	2.82	30.25	60.50
Male	22,593	22,593	70,066	2,178,607	2,192,313	6,389.6	23	22,511,332	22,253,849.4	1.00	96.43	3.10	31.09	36.00
Unknown	3	3	4	230	230	0.7	0	1,629	1,452.9	1.84	76.67	1.33	57.50	0.00
Event Definition 3														
Female	17,028	17,028	47,939	1,450,278	1,460,208	4,297.3	23	23,262,445	23,186,623.9	0.73	85.17	2.82	30.25	53.52
Male	22,593	22,593	70,066	2,178,607	2,192,313	6,390.6	14	22,511,332	22,253,849.4	1.00	96.43	3.10	31.09	21.91
Unknown	3	3	4	230	230	0.7	0	1,629	1,452.9	1.84	76.67	1.33	57.50	0.00
Sulfonylurea														
Event Definition 1														
Female	104,902	104,902	252,357	11,407,742	17,164,195	33,364.1	97	22,984,438	22,780,172.7	4.56	108.75	2.41	45.20	29.07
Male	122,693	122,693	312,381	14,109,799	21,693,639	41,094.4	114	22,144,481	21,739,909.3	5.54	115.00	2.55	45.17	27.74
Unknown	7	7	18	852	1,356	2.5	0	1,601	1,410.4	4.37	121.71	2.57	47.33	0.00
Event Definition 2														
Female	104,902	104,902	252,357	11,407,742	17,164,195	33,365.8	88	22,984,438	22,780,172.7	4.56	108.75	2.41	45.20	26.37
Male	122,693	122,693	312,381	14,109,799	21,693,639	41,094.9	107	22,144,481	21,739,909.3	5.54	115.00	2.55	45.17	26.04
Unknown	7	7	18	852	1,356	2.5	0	1,601	1,410.4	4.37	121.71	2.57	47.33	0.00
Event Definition 3														
Female	104,902	104,902	252,357	11,407,742	17,164,195	33,379.4	33	22,984,438	22,780,172.7	4.56	108.75	2.41	45.20	9.89
Male	122,693	122,693	312,381	14,109,799	21,693,639	41,110.7	38	22,144,481	21,739,909.3	5.54	115.00	2.55	45.17	9.24
Unknown	7	7	18	852	1,356	2.5	0	1,601	1,410.4	4.37	121.71	2.57	47.33	0.00
Saxagliptin or Sitagliptin														
Event Definition 1														
Female	41,481	41,481	108,347	3,823,862	4,482,814	11,386.5	40	23,181,298	23,076,983.3	1.79	92.18	2.61	35.29	35.13
Male	51,657	51,657	138,274	4,968,924	5,979,924	14,755.0	37	22,398,363	22,106,166.9	2.31	96.19	2.68	35.94	25.08
Unknown	4	4	4	181	301	0.6	0	1,618	1,440.7	2.47	45.25	1.00	45.25	0.00

Table 3a. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of the Exposure Drug Class of Interest, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Sex

Sex	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
Event Definition 2														
Female	41,481	41,481	108,347	3,823,862	4,482,814	11,387.7	36	23,181,298	23,076,983.3	1.79	92.18	2.61	35.29	31.61
Male	51,657	51,657	138,274	4,968,924	5,979,924	14,755.0	35	22,398,363	22,106,166.9	2.31	96.19	2.68	35.94	23.72
Unknown	4	4	4	181	301	0.6	0	1,618	1,440.7	2.47	45.25	1.00	45.25	0.00
Event Definition 3														
Female	41,481	41,481	108,347	3,823,862	4,482,814	11,390.3	19	23,181,298	23,076,983.3	1.79	92.18	2.61	35.29	16.68
Male	51,657	51,657	138,274	4,968,924	5,979,924	14,758.1	18	22,398,363	22,106,166.9	2.31	96.19	2.68	35.94	12.20
Unknown	4	4	4	181	301	0.6	0	1,618	1,440.7	2.47	45.25	1.00	45.25	0.00

¹Refer to Appendix B for a list of event definitions.

Table 3b. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of Any Exposure Drug Class, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Sex

Sex	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
SGLT-2 Inhibitors														
Event Definition 1														
Female	8,246	8,246	22,024	656,493	660,537	1,950.4	21	22,924,233	22,713,834.2	0.36	79.61	2.67	29.81	107.67
Male	9,246	9,246	27,068	829,006	833,961	2,440.6	14	22,066,700	21,653,077.1	0.42	89.66	2.93	30.63	57.36
Unknown	0	0	0	0	0	0.0	0	1,597	1,406.3	0.00	---	---	---	---
Event Definition 2														
Female	8,246	8,246	22,024	656,493	660,537	1,951.8	15	22,924,233	22,713,834.2	0.36	79.61	2.67	29.81	76.85
Male	9,246	9,246	27,068	829,006	833,961	2,440.7	12	22,066,700	21,653,077.1	0.42	89.66	2.93	30.63	49.17
Unknown	0	0	0	0	0	0.0	0	1,597	1,406.3	0.00	---	---	---	---
Event Definition 3														
Female	8,246	8,246	22,024	656,493	660,537	1,951.0	16	22,924,233	22,713,834.2	0.36	79.61	2.67	29.81	82.01
Male	9,246	9,246	27,068	829,006	833,961	2,441.0	9	22,066,700	21,653,077.1	0.42	89.66	2.93	30.63	36.87
Unknown	0	0	0	0	0	0.0	0	1,597	1,406.3	0.00	---	---	---	---
Event Definition 1 (No Truncation on Incident Exposure)														
Female	8,246	8,246	22,417	671,513	675,897	1,996.2	21	22,924,233	22,713,834.2	0.36	81.43	2.72	29.96	105.20
Male	9,246	9,246	27,665	851,406	856,937	2,507.3	14	22,066,700	21,653,077.1	0.42	92.08	2.99	30.78	55.84
Unknown	0	0	0	0	0	0.0	0	1,597	1,406.3	0.00	---	---	---	---
Sulfonylurea														
Event Definition 1														
Female	93,742	93,742	217,739	10,060,649	15,174,140	29,423.0	87	22,924,231	22,708,488.0	4.09	107.32	2.32	46.21	29.57
Male	107,664	107,664	264,565	12,231,467	18,847,050	35,606.3	103	22,066,700	21,648,782.7	4.88	113.61	2.46	46.23	28.93
Unknown	7	7	18	852	1,356	2.5	0	1,597	1,405.8	4.38	121.71	2.57	47.33	0.00
Event Definition 2														
Female	93,742	93,742	217,739	10,060,649	15,174,140	29,424.4	79	22,924,231	22,708,488.0	4.09	107.32	2.32	46.21	26.85
Male	107,664	107,664	264,565	12,231,467	18,847,050	35,606.8	96	22,066,700	21,648,782.7	4.88	113.61	2.46	46.23	26.96
Unknown	7	7	18	852	1,356	2.5	0	1,597	1,405.8	4.38	121.71	2.57	47.33	0.00
Event Definition 3														
Female	93,742	93,742	217,739	10,060,649	15,174,140	29,437.7	28	22,924,231	22,708,488.0	4.09	107.32	2.32	46.21	9.51
Male	107,664	107,664	264,565	12,231,467	18,847,050	35,621.3	34	22,066,700	21,648,782.7	4.88	113.61	2.46	46.23	9.54
Unknown	7	7	18	852	1,356	2.5	0	1,597	1,405.8	4.38	121.71	2.57	47.33	0.00

Table 3b. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of Any Exposure Drug Class, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Sex

Sex	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
Event Definition 1 (No Truncation on Incident Exposure)														
Female	93,742	93,742	220,738	10,209,469	15,424,475	29,861.0	88	22,924,231	22,708,488.0	4.09	108.91	2.35	46.25	29.47
Male	107,664	107,664	268,548	12,426,083	19,184,845	36,179.2	104	22,066,700	21,648,782.7	4.88	115.42	2.49	46.27	28.75
Unknown	7	7	18	852	1,356	2.5	0	1,597	1,405.8	4.38	121.71	2.57	47.33	0.00
Saxagliptin or Sitagliptin														
Event Definition 1														
Female	24,785	24,785	61,597	2,098,617	2,509,812	6,272.1	26	22,924,233	22,713,016.0	1.08	84.67	2.49	34.07	41.45
Male	30,048	30,048	77,512	2,681,525	3,324,756	7,986.5	23	22,066,700	21,652,233.0	1.36	89.24	2.58	34.59	28.80
Unknown	4	4	4	181	301	0.6	0	1,597	1,406.3	2.50	45.25	1.00	45.25	0.00
Event Definition 2														
Female	24,785	24,785	61,597	2,098,617	2,509,812	6,272.6	25	22,924,233	22,713,016.0	1.08	84.67	2.49	34.07	39.86
Male	30,048	30,048	77,512	2,681,525	3,324,756	7,986.5	22	22,066,700	21,652,233.0	1.36	89.24	2.58	34.59	27.55
Unknown	4	4	4	181	301	0.6	0	1,597	1,406.3	2.50	45.25	1.00	45.25	0.00
Event Definition 3														
Female	24,785	24,785	61,597	2,098,617	2,509,812	6,275.0	10	22,924,233	22,713,016.0	1.08	84.67	2.49	34.07	15.94
Male	30,048	30,048	77,512	2,681,525	3,324,756	7,987.9	11	22,066,700	21,652,233.0	1.36	89.24	2.58	34.59	13.77
Unknown	4	4	4	181	301	0.6	0	1,597	1,406.3	2.50	45.25	1.00	45.25	0.00
Event Definition 1 (No Truncation on Incident Exposure)														
Female	24,785	24,785	64,125	2,212,607	2,649,957	6,613.0	27	22,924,233	22,713,016.0	1.08	89.27	2.59	34.50	40.83
Male	30,048	30,048	80,708	2,827,808	3,509,972	8,424.6	24	22,066,700	21,652,233.0	1.36	94.11	2.69	35.04	28.49
Unknown	4	4	4	181	301	0.6	0	1,597	1,406.3	2.50	45.25	1.00	45.25	0.00

¹Refer to Appendix B for a list of event definitions.

Table 4a. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of the Exposure Drug Class of Interest, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Year

Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
SGLT-2 Inhibitors														
Event Definition 1														
2013	14,471	14,471	60,747	1,973,739	1,986,587	5,788.0	24	39,500,548	24,808,920.2	0.37	136.39	4.20	32.49	41.47
2014	25,138	25,138	57,243	1,654,738	1,665,526	4,896.6	34	35,793,111	19,801,641.9	0.70	65.83	2.28	28.91	69.44
2015	15	15	19	638	638	1.8	0	3,759,319	831,364.0	0.00	42.53	1.27	33.58	0.00
Event Definition 2														
2013	14,471	14,471	60,747	1,973,739	1,986,587	5,788.9	21	39,500,548	24,808,920.2	0.37	136.39	4.20	32.49	36.28
2014	25,138	25,138	57,243	1,654,738	1,665,526	4,897.3	28	35,793,111	19,801,641.9	0.70	65.83	2.28	28.91	57.17
2015	15	15	19	638	638	1.8	0	3,759,319	831,364.0	0.00	42.53	1.27	33.58	0.00
Event Definition 3														
2013	14,471	14,471	60,747	1,973,739	1,986,587	5,788.8	16	39,500,548	24,808,920.2	0.37	136.39	4.20	32.49	27.64
2014	25,138	25,138	57,243	1,654,738	1,665,526	4,898.0	21	35,793,111	19,801,641.9	0.70	65.83	2.28	28.91	42.88
2015	15	15	19	638	638	1.8	0	3,759,319	831,364.0	0.00	42.53		33.58	0.00
Sulfonylurea														
Event Definition 1														
2013	123,183	123,183	366,150	16,672,939	25,258,595	48,629.0	127	38,882,870	24,319,952.4	3.17	135.35	2.97	45.54	26.12
2014	99,515	99,515	193,542	8,637,731	13,267,382	25,259.4	77	35,171,521	19,396,892.9	2.83	86.80	1.94	44.63	30.48
2015	4,904	4,904	5,064	207,723	333,213	572.5	7	3,647,307	804,647.1	1.34	42.36	1.03	41.02	122.27
Event Definition 2														
2013	123,183	123,183	366,150	16,672,939	25,258,595	48,630.9	114	38,882,870	24,319,952.4	3.17	135.35	2.97	45.54	23.44
2014	99,515	99,515	193,542	8,637,731	13,267,382	25,259.7	74	35,171,521	19,396,892.9	2.83	86.80	1.94	44.63	29.30
2015	4,904	4,904	5,064	207,723	333,213	572.5	7	3,647,307	804,647.1	1.34	42.36	1.03	41.02	122.27
Event Definition 3														
2013	123,183	123,183	366,150	16,672,939	25,258,595	48,649.0	41	38,882,870	24,319,952.4	3.17	135.35	2.97	45.54	8.43
2014	99,515	99,515	193,542	8,637,731	13,267,382	25,270.5	29	35,171,521	19,396,892.9	2.83	86.80	1.94	44.63	11.48
2015	4,904	4,904	5,064	207,723	333,213	573.1	1	3,647,307	804,647.1	1.34	42.36	1.03	41.02	17.45
Saxagliptin or Sitagliptin														
Event Definition 1														
2013	53,300	53,300	166,389	6,147,500	7,286,880	18,244.0	50	39,308,165	24,651,654.1	1.36	115.34	3.12	36.95	27.41
2014	39,817	39,817	80,207	2,644,444	3,175,112	7,895.1	27	35,617,042	19,701,726.8	1.12	66.41	2.01	32.97	34.20
2015	25	25	29	1,023	1,048	2.9	0	3,758,736	831,210.1	0.01	40.92	1.16	35.28	0.00

Table 4a. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of the Exposure Drug Class of Interest, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Year

Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
Event Definition 2														
2013	53,300	53,300	166,389	6,147,500	7,286,880	18,245.2	46	39,308,165	24,651,654.1	1.36	115.34	3.12	36.95	25.21
2014	39,817	39,817	80,207	2,644,444	3,175,112	7,895.2	25	35,617,042	19,701,726.8	1.12	66.41	2.01	32.97	31.66
2015	25	25	29	1,023	1,048	2.9	0	3,758,736	831,210.1	0.01	40.92	1.16	35.28	0.00
Event Definition 3														
2013	53,300	53,300	166,389	6,147,500	7,286,880	18,249.3	24	39,308,165	24,651,654.1	1.36	115.34	3.12	36.95	13.15
2014	39,817	39,817	80,207	2,644,444	3,175,112	7,896.8	13	35,617,042	19,701,726.8	1.12	66.41	2.01	32.97	16.46
2015	25	25	29	1,023	1,048	2.9	0	3,758,736	831,210.1	0.01	40.92	1.16	35.28	0.00

¹Refer to Appendix B for a list of event definitions.

Table 4b. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of Any Exposure Drug Class, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Year

Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
SGLT-2 Inhibitors														
Event Definition 1														
2013	6,135	6,135	24,337	779,321	784,568	2,292.5	16	38,757,431	24,226,339.1	0.16	127.03	3.97	32.02	69.79
2014	11,351	11,351	24,746	705,893	709,645	2,097.6	19	35,078,313	19,335,974.8	0.32	62.19	2.18	28.53	90.58
2015	6	6	9	285	285	0.8	0	3,654,660	806,003.8	0.00	47.50	1.50	31.67	0.00
Event Definition 2														
2013	6,135	6,135	24,337	779,321	784,568	2,293.3	14	38,757,431	24,226,339.1	0.16	127.03	3.97	32.02	61.05
2014	11,351	11,351	24,746	705,893	709,645	2,098.4	13	35,078,313	19,335,974.8	0.32	62.19	2.18	28.53	61.95
2015	6	6	9	285	285	0.8	0	3,654,660	806,003.8	0.00	47.50	1.50	31.67	0.00
Event Definition 3														
2013	6,135	6,135	24,337	779,321	784,568	2,293.0	11	38,757,431	24,226,339.1	0.16	127.03	3.97	32.02	47.97
2014	11,351	11,351	24,746	705,893	709,645	2,098.2	14	35,078,313	19,335,974.8	0.32	62.19	2.18	28.53	66.72
2015	6	6	9	285	285	0.8	0	3,654,660	806,003.8	0.00	47.50	1.50	31.67	0.00
Event Definition 1 (No Truncation on Incident Exposure)														
2013	6,135	6,135	24,992	803,255	809,120	2,364.1	16	38,757,431	24,226,339.1	0.16	130.93	4.07	32.14	67.68
2014	11,351	11,351	25,081	719,379	723,429	2,138.6	19	35,078,313	19,335,974.8	0.32	63.38	2.21	28.68	88.84
2015	6	6	9	285	285	0.8	0	3,654,660	806,003.8	0.00	47.50	1.50	31.67	0.00
Sulfonylurea														
Event Definition 1														
2013	107,639	107,639	307,939	14,327,231	21,742,688	41,787.0	114	38,757,431	24,226,107.5	2.78	133.10	2.86	46.53	27.28
2014	88,876	88,876	169,326	7,758,345	11,947,256	22,673.2	69	35,054,893	19,327,964.0	2.54	87.29	1.91	45.82	30.43
2015	4,898	4,898	5,057	207,392	332,602	571.6	7	3,647,065	804,605.0	1.34	42.34	1.03	41.01	122.47
Event Definition 2														
2013	107,639	107,639	307,939	14,327,231	21,742,688	41,788.6	102	38,757,431	24,226,107.5	2.78	133.10	2.86	46.53	24.41
2014	88,876	88,876	169,326	7,758,345	11,947,256	22,673.5	66	35,054,893	19,327,964.0	2.54	87.29	1.91	45.82	29.11
2015	4,898	4,898	5,057	207,392	332,602	571.6	7	3,647,065	804,605.0	1.34	42.34	1.03	41.01	122.47
Event Definition 3														
2013	107,639	107,639	307,939	14,327,231	21,742,688	41,805.6	35	38,757,431	24,226,107.5	2.78	133.10	2.86	46.53	8.37
2014	88,876	88,876	169,326	7,758,345	11,947,256	22,683.6	26	35,054,893	19,327,964.0	2.54	87.29	1.91	45.82	11.46
2015	4,898	4,898	5,057	207,392	332,602	572.2	1	3,647,065	804,605.0	1.34	42.34	1.03	41.01	17.48

Table 4b. Summary of New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin, with No Prior Use of Any Exposure Drug Class, in the Mini-Sentinel Distributed Database (MSDD) between April 1, 2013 and March 31, 2015, by Event Definition¹ and Year

Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
Event Definition 1 (No Truncation on Incident Exposure)														
2013	107,639	107,639	313,373	14,590,430	22,200,014	42,557.1	116	38,757,431	24,226,107.5	2.78	135.55	2.91	46.56	27.26
2014	88,876	88,876	170,874	7,838,568	12,078,044	22,914.0	69	35,054,893	19,327,964.0	2.54	88.20	1.92	45.87	30.11
2015	4,898	4,898	5,057	207,406	332,616	571.6	7	3,647,065	804,605.0	1.34	42.35	1.03	41.01	122.46
Saxagliptin or Sitagliptin														
Event Definition 1														
2013	31,305	31,305	93,220	3,307,616	4,021,741	9,847.9	29	38,757,431	24,226,264.7	0.81	105.66	2.98	35.48	29.45
2014	23,524	23,524	45,883	1,472,294	1,812,751	4,410.1	20	35,073,148	19,334,403.1	0.67	62.59	1.95	32.09	45.35
2015	8	8	10	413	378	1.1	0	3,654,567	805,987.6	0.00	51.63	1.25	41.30	0.00
Event Definition 2														
2013	31,305	31,305	93,220	3,307,616	4,021,741	9,848.4	28	38,757,431	24,226,264.7	0.81	105.66	2.98	35.48	28.43
2014	23,524	23,524	45,883	1,472,294	1,812,751	4,410.1	19	35,073,148	19,334,403.1	0.67	62.59	1.95	32.09	43.08
2015	8	8	10	413	378	1.1	0	3,654,567	805,987.6	0.00	51.63	1.25	41.30	0.00
Event Definition 3														
2013	31,305	31,305	93,220	3,307,616	4,021,741	9,851.1	13	38,757,431	24,226,264.7	0.81	105.66	2.98	35.48	13.20
2014	23,524	23,524	45,883	1,472,294	1,812,751	4,411.3	8	35,073,148	19,334,403.1	0.67	62.59	1.95	32.09	18.14
2015	8	8	10	413	378	1.1	0	3,654,567	805,987.6	0.00	51.63	1.25	41.30	0.00
Event Definition 1 (No Truncation on Incident Exposure)														
2013	31,305	31,305	97,729	3,508,663	4,271,191	10,444.2	31	38,757,431	24,226,264.7	0.81	112.08	3.12	35.90	29.68
2014	23,524	23,524	47,098	1,531,520	1,888,662	4,592.8	20	35,073,148	19,334,403.1	0.67	65.10	2.00	32.52	43.55
2015	8	8	10	413	378	1.1	0	3,654,567	805,987.6	0.00	51.63	1.25	41.30	0.00

¹Refer to Appendix B for a list of event definitions.

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 26, 2015)

DP ID	DP Start Date*	DP End Date*
DP01	01/01/2000	08/31/2014
DP02	01/01/2004	10/31/2014
DP03	01/01/2000	03/31/2015
DP04	01/01/2000	10/31/2014
DP05	01/01/2000	05/31/2014
DP06	01/01/2000	10/31/2014
DP07	01/01/2008	09/30/2014
DP08	01/01/2005	04/30/2014
DP09	01/01/2008	12/31/2014
DP10	01/01/2000	04/30/2014
DP11	06/01/2007	07/31/2014
DP12	01/02/2000	07/31/2014
DP13	01/01/2006	04/30/2014

*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. Generic and Brand Names of Medical Products Used to Define Exposures of Interest in this Request

Generic Name	Brand Name
Canagliflozin	Invokana
Canagliflozin/metformin HCl	Invokamet
Dapagliflozin propanediol	Farxiga
Dapagliflozin propanediol/metformin HCl	Xigduo XR
Rosiglitazone maleate/glimepiride	Avandaryl
Glyburide, micronized	Glynase
Glyburide	Diabeta
Glimepiride	Amaryl
Glipizide	Glucotrol XL
Glipizide	Glucotrol
Glyburide/metformin HCl	Glucovance
Glipizide/metformin HCl	Metaglip
Glyburide/metformin HCl	Glyburide-Metformin
Glimepiride	Glimepiride
Glipizide/metformin HCl	Glipizide-Metformin
Glyburide, micronized	Glyburide Micronized
Glyburide	Glyburide
Glipizide	Glipizide
Chlorpropamide	Chlorpropamide
Tolbutamide	Tolbutamide
Tolazamide	Tolazamide
Pioglitazone HCl/glimepiride	Pioglitazone-Glimepiride
Pioglitazone HCl/glimepiride	Duetact
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
Empagliflozin	Jardiance

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Outcomes used in this Request

Code	Description	Code Type	Code Category
Diabetic Ketoacidosis Definition 1			
250.1	Diabetes with ketoacidosis	ICD-9-CM	Diagnosis
Diabetic Ketoacidosis Definition 2			
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
Diabetic Ketoacidosis Definition 3			
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis

Appendix D. Specifications Defining Parameters in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 2.0.5 to estimate the rate of diabetic ketoacidosis (DKA) among new users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Sulfonylureas, Saxagliptin, and Sitagliptin in the Mini-Sentinel Distributed Database (MSDD).

Query Period: April 1, 2013 to March 31, 2015

Enrollment Gap: 45 days

Age Groups: 0-21, 22-44, 45-64, 65+ years

Enrollment Requirement: 183 days

Coverage Requirement: Medical and Drug Coverage

Scenario	Drug/Exposure								Outcome							
	Incident Exposure	Incident with Respect to:	Truncate on Incident Exposure	Washout (days)	Cohort Definition	Episode Gap (days)	Episode Extension (days)	Minimum Episode Duration (days)	Minimum Days Supply (days)	Censor at Evidence of Death	Outcome (ICD-9 CM code)	Care Setting	Washout (days)	Incident with Respect to:	Incident Care Setting	Blackout Period (days)
1	Canagliflozin, Dapagliflozin (with combination products)	Any SGLT-2 Inhibitor*	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	Inpatient (IP)	90	DKA Definition 1	IP	0
2	Canagliflozin, Dapagliflozin (with combination products)	Any SGLT-2 Inhibitor	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 2	IP	90	DKA Definition 1	IP	0
3	Canagliflozin, Dapagliflozin (with combination products)	Any SGLT-2 Inhibitor	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 3	IP	90	DKA Definition 1	IP	0
4	Canagliflozin, Dapagliflozin (with combination products)	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	IP	90	DKA Definition 1	IP	0
5	Canagliflozin, Dapagliflozin (with combination products)	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 2	IP	90	DKA Definition 1	IP	0

Appendix D. Specifications Defining Parameters in this Request

Scenario	Drug/Exposure										Outcome					
	Incident Exposure	Incident with Respect to:	Truncate on Incident Exposure	Washout (days)	Cohort Definition	Episode Gap (days)	Episode Extension (days)	Minimum Episode Duration (days)	Minimum Days Supply (days)	Censor at Evidence of Death	Outcome (ICD-9 CM code)	Care Setting	Washout (days)	Incident with Respect to:	Incident Care Setting	Blackout Period (days)
6	Canagliflozin, Dapagliflozin (with combination products)	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 3	IP	90	DKA Definition 1	IP	0
7	Sulfonylureas	Sulfonylureas	N/A	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	IP	90	DKA Definition 1	IP	0
8	Sulfonylureas	Sulfonylureas	N/A	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 2	IP	90	DKA Definition 1	IP	0
9	Sulfonylureas	Sulfonylureas	N/A	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 3	IP	90	DKA Definition 1	IP	0
10	Sulfonylureas	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	IP	90	DKA Definition 1	IP	0
11	Sulfonylureas	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 2	IP	90	DKA Definition 1	IP	0
12	Sulfonylureas	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 3	IP	90	DKA Definition 1	IP	0

Appendix D. Specifications Defining Parameters in this Request

Scenario	Drug/Exposure										Outcome					
	Incident Exposure	Incident with Respect to:	Truncate on Incident Exposure	Washout (days)	Cohort Definition	Episode Gap (days)	Episode Extension (days)	Minimum Episode Duration (days)	Minimum Days Supply (days)	Censor at Evidence of Death	Outcome (ICD-9 CM code)	Care Setting	Washout (days)	Incident with Respect to:	Incident Care Setting	Blackout Period (days)
13	Sitagliptin or Saxagliptin	Sitagliptin or Saxagliptin	N/A	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	IP	90	DKA Definition 1	IP	0
14	Sitagliptin or Saxagliptin	Sitagliptin or Saxagliptin	N/A	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 2	IP	90	DKA Definition 1	IP	0
15	Sitagliptin or Saxagliptin	Sitagliptin or Saxagliptin	N/A	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 3	IP	90	DKA Definition 1	IP	0
16	Sitagliptin or Saxagliptin	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	IP	90	DKA Definition 1	IP	0
17	Sitagliptin or Saxagliptin	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 2	IP	90	DKA Definition 1	IP	0
18	Sitagliptin or Saxagliptin	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	Yes	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 3	IP	90	DKA Definition 1	IP	0
19	Canagliflozin, Dapagliflozin (with combination products)	Any SGLT-2 Inhibitor, Sulfonylurea, Saxagliptin, or Sitagliptin	No	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	IP	90	DKA Definition 1	IP	0

Appendix D. Specifications Defining Parameters in this Request

Scenario	Drug/Exposure										Outcome					
	Incident Exposure	Incident with Respect to:	Truncate on Incident Exposure	Washout (days)	Cohort Definition	Episode Gap (days)	Episode Extension (days)	Minimum Episode Duration (days)	Minimum Days Supply (days)	Censor at Evidence of Death	Outcome (ICD-9 CM code)	Care Setting	Washout (days)	Incident with Respect to:	Incident Care Setting	Blackout Period (days)
20	Sulfonylureas	Any SGLT-2 Inhibitor , Sulfonylurea, Saxagliptin, or Sitagliptin	No	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	IP	90	DKA Definition 1	IP	0
21	Sitagliptin or Saxagliptin	Any SGLT-2 Inhibitor , Sulfonylurea, Saxagliptin, or Sitagliptin	No	183	Include only the first valid exposure	10	10	0	0	No	DKA Definition 1	IP	90	DKA Definition 1	IP	0

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

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes are provided by Optum360.

*"Any SGLT-2 Inhibitor " includes empagliflozin in addition to canagliflozin and dapagliflozin