

## 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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**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 Definition<sup>1</sup> 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
<b>Event Definition 1 (No Truncation on Incident Exposure)</b>														
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
<b>Saxagliptin or Sitagliptin</b>														
<b>Event Definition 1</b>														
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
<b>Event Definition 2</b>														
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
<b>Event Definition 3</b>														
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
<b>Event Definition 1 (No Truncation on Incident Exposure)</b>														
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

<sup>1</sup>Refer 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**

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<b>Generic Name</b>	<b>Brand Name</b>
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**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>	<b>Code Category</b>
<b>Diabetic Ketoacidosis Definition 1</b>			
250.1	Diabetes with ketoacidosis	ICD-9-CM	Diagnosis
<b>Diabetic Ketoacidosis Definition 2</b>			
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
<b>Diabetic Ketoacidosis Definition 3</b>			
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**

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