



Modular Program Report

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).

If you are using a web page screen reader and are unable to access this document, please contact the Mini-Sentinel Operations Center for assistance at info@mini-sentinel.org.

Overview

Request Description

In June of 2013, FDA requested de novo programming to assess serious hypoglycemic events following use of anti-diabetic agents (ADAs). The request ID was MSY4_AH4. The program was based on Modular Program #3 (v6.0). The exposure and inclusion/exclusion portions of the program are original MP3 programming. The event portion of the program consists of de novo programming to classify events into two types of hypoglycemic events based on a validated algorithm. The modified MP3 outputs a few additional metrics for each of the two types of hypoglycemic events: event classification (NumEvents1, NumEvents2) and time-to-event/days at risk (DaysAtRisk1, DaysAtRisk2). Please see "*Hypoglycemia_DeNovo_Final_Specifications_ah4_08132013.pdf*" for more information.

This report provides results for a new request that makes use of the de novo programming completed for MSY4_AH4. The request is similar in that it examines hypoglycemic events (defined using the same algorithm as in MSY4_AH4) following use of ADAs. However, the ADAs are grouped in slightly different ways. Please see the Specifications tab for a list of scenarios examined in this request. The query was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of January 1, 2004 - December 31, 2012. The request was distributed to 18 Data Partners in November 2013. This report includes results for scenarios 1-17 shown in the Specifications tab. These scenarios do not have a pre-existing dispensing requirement. Results for scenarios 18-30 are presented in a separate report (MSY5_MPR07_V1_Report2) and use different incidence criteria.

Request ID MSY5_MPR07_v1 Report 1 of 2

Specifications Program parameter inputs and scenarios

Glossary List of terms found in this report and their definitions

Table 1 Table of Summary of Incident ADA Use and Hypoglycemia in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product

Table 2 Table of Summary of Incident ADA Use and Hypoglycemia in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

Table 3 Table of Summary of Incident ADA Use and Hypoglycemia in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

Table 4 Table of Summary of Incident ADA Use and Hypoglycemia in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

Notes: Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications MSY5_MPR07_v1 - Hypoglycemia and ADAs

This report provides results for a new request that makes use of the de novo programming completed for MSY4_AH4. The request is similar in that it examines hypoglycemic events (defined using the same algorithm as in MSY4_AH4) following use of ADAs; however, the ADAs are grouped in slightly different ways. Please refer to Hypoglycemia_DeNovo_Final_Specifications_ah4_08132013.pdf for event algorithm and additional information. This report presents scenarios 1-17. Please see MS_Brief_Report_MSYS_MPR07_v1_part2 for results on Scenarios 18-30.

Query dates January 1, 2004 - December 31, 2012 00-34
 Age Stratifications 35-49 50-64 65-79 80+
 Coverage Requirement Medical and Drug
 Enrollment Gap 45 Days

Drug/Exposure

Scenario	Incident exposure	Incident w/ respect to:	Washout (days)	Incidence Type	Episode Gap	Exposure Extension Period	Minimum Days Supplied
1	Chlorpropamide	All ADAs	183	SING	10	10	1
2	Glimepiride	All ADAs	183	SING	10	10	1
3	Glipizide	All ADAs	183	SING	10	10	1
4	Glipizide/Metformin	All ADAs	183	SING	10	10	1
5	Glyburide	All ADAs	183	SING	10	10	1
6	Glyburide/Metformin	All ADAs	183	SING	10	10	1
7	Tolazamide	All ADAs	183	SING	10	10	1
8	Pioglitazone	All ADAs	183	SING	10	10	1
9	Pioglitazone/Metformin	All ADAs	183	SING	10	10	1
10	Rosiglitazone Maleate	All ADAs	183	SING	10	10	1
11	Rosiglitazone/Metformin	All ADAs	183	SING	10	10	1
12	Insulin (Rapid-Acting)	All ADAs	183	SING	10	10	1
13	Insulin (Short-Acting)	All ADAs	183	SING	10	10	1
14	Insulin (Long-Acting)	All ADAs	183	SING	10	10	1
15	Insulin (Intermediate-Acting)	All ADAs	183	SING	10	10	1
16	Insulin (Intermediate/Rapid-Acting)	All ADAs	183	SING	10	10	1
17	Insulin (Intermediate/Short-Acting)	All ADAs	183	SING	10	10	1
18	Chlorpropamide	All ADAs except Metformin	183	SING	10	10	1
19	Glimepiride	All ADAs except Metformin	183	SING	10	10	1
20	Glipizide/Glipizide-Metformin	All ADAs except Metformin	183	SING	10	10	1
21	Glyburide/Glyburide-Metformin	All ADAs except Metformin	183	SING	10	10	1
22	Tolazamide	All ADAs except Metformin	183	SING	10	10	1
23	Pioglitazone/Pioglitazone-Metformin	All ADAs except Metformin	183	SING	10	10	1
24	Rosiglitazone Maleate/Rosiglitazone-Metformin	All ADAs except Metformin	183	SING	10	10	1
25	Insulin (Rapid-Acting)	All ADAs except Metformin	183	SING	10	10	1
26	Insulin (Short-Acting)	All ADAs except Metformin	183	SING	10	10	1
27	Insulin (Long-Acting)	All ADAs except Metformin	183	SING	10	10	1
28	Insulin (Intermediate-Acting)	All ADAs except Metformin	183	SING	10	10	1
29	Insulin (Intermediate/Rapid-Acting)	All ADAs except Metformin	183	SING	10	10	1
30	Insulin (Intermediate/Short-Acting)	All ADAs except Metformin	183	SING	10	10	1

*Requires de novo programming. See event algorithm.

** Program will consider only the first incident episode. All subsequent episodes will be excluded from the analysis.

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

ICD-9-CM diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

HCPCS codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

CPT codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

Glossary of Terms in Modular Program 3*

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).

Days at Risk - number of days supplied plus any episode gaps and exposure extension periods.

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

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

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

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

Incidence Type (drug/exposure)- *Minimum incidence type* will consider the first treatment episode in the query period as long as it is the first treatment episode in the user's entire available history. *Single* and *Multiple incidence types* will use the washout period to establish incidence, however *Single* will only consider the first treatment episode whereas *Multiple* will consider all qualifying incident treatment episodes.

Incidence Type (event/outcome)- *Minimum incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple incidence type* uses the washout period to establish incidence and considers all qualifying incident treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident episode.

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

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

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

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

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

Principal Diagnosis - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. YES will only consider diagnoses flagged as Principal

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

Time to Event - time in days between treatment initiation and event.

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

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

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

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

*all terms may not be used in this report

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

**Table 1: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012,
by ADA Product**

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1
Insulin (Rapid-Acting)	125,289	125,289	186,380	6,678,029	6,970,833	19,085	1,034	331	703	14,817
Insulin (Short-Acting)	0	0	0	0	0	0	0	0	0	0
Insulin (Long-Acting)	106,879	106,879	154,120	5,605,570	5,657,409	15,489	717	186	531	9,114
Insulin (Intermediate-Acting)	52,580	52,580	81,779	2,872,812	3,008,466	8,237	353	124	229	6,683
Insulin (Intermediate/Rapid-Acting)	12,394	12,394	21,981	797,124	841,843	2,305	155	47	108	3,037
Insulin (Intermediate/Short-Acting)	2	2	2	35	55	0	0	0	0	0
Chlorpropamide	256	256	844	37,816	38,907	107	0	0	0	0
Glimepiride	80,860	80,860	245,338	9,477,324	9,532,427	26,098	342	98	244	11,682
Glipizide	171,070	171,070	534,739	27,117,280	26,631,098	72,912	1,215	354	861	63,622
Glipizide/Metformin	4,254	4,254	12,557	497,705	511,359	1,400	16	2	14	207
Glyburide	120,536	120,536	312,315	13,797,697	13,928,750	38,135	660	235	425	21,580
Glyburide/Metformin	31,081	31,081	94,264	3,460,397	3,592,144	9,835	113	29	84	2,921
Tolazamide	8,140	8,140	20,095	1,726,227	1,660,635	4,547	62	45	17	7,113
Pioglitazone	66,334	66,334	200,511	7,918,382	8,049,685	22,039	169	38	131	2,523
Pioglitazone/Metformin	20,182	20,182	56,016	2,076,352	2,187,323	5,989	17	3	14	85
Rosiglitazone Maleate	14,780	14,780	42,474	1,535,800	1,569,105	4,296	36	10	26	1,151
Rosiglitazone/Metformin	10,994	10,994	31,640	1,134,702	1,181,648	3,235	16	5	11	193

Table 1: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product

	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1000 Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/ 1000 Years at Risk
Insulin (Rapid-Acting)	32,176	86,431,405	73,658,494,483	1.4	53.3	1.5	35.8	14.8	54.2
Insulin (Short-Acting)	0	86,423,695	73,675,452,822	0.0	---	---	---	---	---
Insulin (Long-Acting)	24,536	86,432,700	73,668,051,548	1.2	52.4	1.4	36.4	12.7	46.3
Insulin (Intermediate-Acting)	12,292	86,427,310	73,664,205,983	0.6	54.6	1.6	35.1	11.7	42.9
Insulin (Intermediate/Rapid-Acting)	9,085	86,424,821	73,673,712,052	0.1	64.3	1.8	36.3	18.4	67.2
Insulin (Intermediate/Short-Acting)	0	86,423,695	73,675,450,274	0.0	17.5	1.0	17.5	0.0	0.0
Chlorpropamide	0	86,423,718	73,675,365,724	0.0	147.7	3.3	44.8	0.0	0.0
Glimepiride	28,053	86,429,621	73,669,233,687	0.9	117.2	3.0	38.6	3.6	13.1
Glipizide	204,966	86,434,580	73,657,692,021	2.0	158.5	3.1	50.7	4.6	16.7
Glipizide/Metformin	1,517	86,423,848	73,675,131,784	0.0	117.0	3.0	39.6	3.1	11.4
Glyburide	47,449	86,432,017	73,651,560,158	1.4	114.5	2.6	44.2	4.7	17.3
Glyburide/Metformin	7,336	86,425,233	73,672,738,451	0.4	111.3	3.0	36.7	3.1	11.5
Tolazamide	5,399	86,425,316	73,674,102,646	0.1	212.1	2.5	85.9	3.7	13.6
Pioglitazone	20,456	86,432,668	73,667,548,812	0.8	119.4	3.0	39.5	2.1	7.7
Pioglitazone/Metformin	1,234	86,424,406	73,673,163,696	0.2	102.9	2.8	37.1	0.8	2.8
Rosiglitazone Maleate	1,007	86,426,052	73,672,887,129	0.2	103.9	2.9	36.2	2.3	8.4
Rosiglitazone/Metformin	343	86,424,218	73,673,380,535	0.1	103.2	2.9	35.9	1.4	4.9

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1
Insulin (Rapid-Acting)										
00 to 34	33,351	33,351	54,931	2,012,056	2,062,666	5,647	288	99	189	5,144
35 to 49	28,005	28,005	41,196	1,501,580	1,571,001	4,301	219	69	150	3,233
50 to 64	34,920	34,920	51,136	1,877,253	1,946,088	5,328	284	84	200	3,740
65 to 79	20,177	20,177	27,848	981,565	1,044,390	2,859	173	55	118	1,426
80+	8,836	8,836	11,269	305,575	346,688	949	70	24	46	1,274
Insulin (Short-Acting)										
00 to 34	0	0	0	0	0	0	0	0	0	0
35 to 49	0	0	0	0	0	0	0	0	0	0
50 to 64	0	0	0	0	0	0	0	0	0	0
65 to 79	0	0	0	0	0	0	0	0	0	0
80+	0	0	0	0	0	0	0	0	0	0
Insulin (Long-Acting)										
00 to 34	21,290	21,290	30,757	1,080,636	1,068,432	2,925	190	56	134	2,303
35 to 49	24,835	24,835	34,099	1,169,031	1,196,562	3,276	150	32	118	2,360
50 to 64	36,503	36,503	53,334	1,939,700	1,962,905	5,374	195	52	143	2,820
65 to 79	18,824	18,824	27,963	1,116,980	1,121,980	3,072	127	32	95	1,082
80+	5,427	5,427	7,967	299,223	307,530	842	55	14	41	549
Insulin (Intermediate-Acting)										
00 to 34	15,265	15,265	21,992	716,041	760,508	2,082	61	23	38	709
35 to 49	13,021	13,021	19,077	632,410	660,178	1,807	63	19	44	696
50 to 64	12,100	12,100	19,715	722,630	746,766	2,045	94	32	62	2,574
65 to 79	8,915	8,915	15,257	580,175	608,532	1,666	87	29	58	1,720
80+	3,279	3,279	5,738	221,556	232,482	637	48	21	27	984

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Insulin (Rapid-Acting)									
00 to 34	10,369	45,260,831	34,199,667,580	0.7	60.3	1.6	36.6	14.0	51.0
35 to 49	7,431	23,307,212	17,429,131,103	1.2	53.6	1.5	36.4	13.9	50.9
50 to 64	8,574	17,792,355	14,892,216,679	2.0	53.8	1.5	36.7	14.6	53.3
65 to 79	4,511	5,973,703	5,338,811,143	3.4	48.6	1.4	35.2	16.6	60.5
80+	1,291	1,831,199	1,798,667,978	4.8	34.6	1.3	27.1	20.2	73.7
Insulin (Short-Acting)									
00 to 34	0	45,260,046	34,203,477,432	0.0	---	---	---	---	---
35 to 49	0	23,308,004	17,433,696,263	0.0	---	---	---	---	---
50 to 64	0	17,791,341	14,896,505,257	0.0	---	---	---	---	---
65 to 79	0	5,972,512	5,341,542,875	0.0	---	---	---	---	---
80+	0	1,831,428	1,800,230,995	0.0	---	---	---	---	---
Insulin (Long-Acting)									
00 to 34	4,706	45,260,645	34,202,037,254	0.5	50.8	1.4	35.1	17.8	65.0
35 to 49	4,479	23,308,625	17,431,805,354	1.1	47.1	1.4	34.3	12.5	45.8
50 to 64	8,078	17,793,303	14,894,041,993	2.1	53.1	1.5	36.4	9.9	36.3
65 to 79	4,506	5,974,842	5,340,429,045	3.2	59.3	1.5	39.9	11.3	41.3
80+	2,767	1,831,795	1,799,737,902	3.0	55.1	1.5	37.6	17.9	65.3
Insulin (Intermediate-Acting)									
00 to 34	1,516	45,260,303	34,199,828,359	0.3	46.9	1.4	32.6	8.0	29.3
35 to 49	1,789	23,306,020	17,428,940,502	0.6	48.6	1.5	33.2	9.5	34.9
50 to 64	1,738	17,791,909	14,895,197,896	0.7	59.7	1.6	36.7	12.6	46.0
65 to 79	4,689	5,973,276	5,340,493,726	1.5	65.1	1.7	38.0	14.3	52.2
80+	2,560	1,831,453	1,799,745,500	1.8	67.6	1.7	38.6	20.6	75.4

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1
Insulin (Intermediate/Rapid-Acting)										
00 to 34	1,069	1,069	1,825	56,986	60,165	165	12	5	7	238
35 to 49	2,666	2,666	4,456	148,136	154,411	423	38	6	32	161
50 to 64	4,175	4,175	7,496	273,068	285,290	781	37	16	21	1,761
65 to 79	3,288	3,288	6,391	247,895	264,128	723	48	13	35	387
80+	1,196	1,196	1,813	71,039	77,849	213	20	7	13	490
Insulin (Intermediate/Short-Acting)										
00 to 34	1	1	1	5	15	0	0	0	0	0
35 to 49	0	0	0	0	0	0	0	0	0	0
50 to 64	1	1	1	30	40	0	0	0	0	0
65 to 79	0	0	0	0	0	0	0	0	0	0
80+	0	0	0	0	0	0	0	0	0	0
Chlorpropamide										
00 to 34	25	25	35	1,108	1,302	4	0	0	0	0
35 to 49	47	47	83	3,010	3,367	9	0	0	0	0
50 to 64	59	59	197	7,597	7,636	21	0	0	0	0
65 to 79	74	74	327	15,209	15,593	43	0	0	0	0
80+	51	51	202	10,892	11,009	30	0	0	0	0
Glimepiride										
00 to 34	3,511	3,511	7,070	228,503	235,881	646	9	2	7	318
35 to 49	18,609	18,609	44,389	1,485,977	1,522,526	4,168	49	10	39	258
50 to 64	32,822	32,822	96,625	3,536,305	3,558,711	9,743	87	21	66	2,276
65 to 79	19,659	19,659	70,767	3,129,149	3,106,999	8,506	114	41	73	5,144
80+	6,259	6,259	26,487	1,097,390	1,108,310	3,034	83	24	59	3,686
Glipizide										
00 to 34	7,018	7,018	13,033	583,467	575,925	1,577	43	8	35	264
35 to 49	38,377	38,377	90,544	4,140,183	4,087,663	11,191	182	31	151	2,704
50 to 64	65,229	65,229	194,246	9,393,222	9,184,807	25,147	350	88	262	13,032
65 to 79	43,644	43,644	165,797	9,227,883	9,050,193	24,778	397	138	259	30,628
80+	16,802	16,802	71,119	3,772,525	3,732,510	10,219	243	89	154	16,994

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Insulin (Intermediate/Rapid-Acting)									
00 to 34	138	45,260,077	34,203,271,585	0.0	53.3	1.7	31.2	19.9	72.8
35 to 49	2,498	23,307,958	17,433,300,498	0.1	55.6	1.7	33.2	24.6	89.9
50 to 64	1,552	17,791,450	14,895,928,716	0.2	65.4	1.8	36.4	13.0	47.4
65 to 79	4,460	5,972,780	5,341,173,996	0.6	75.4	1.9	38.8	18.2	66.4
80+	437	1,831,397	1,800,037,257	0.7	59.4	1.5	39.2	25.7	93.8
Insulin (Intermediate/Short-Acting)									
00 to 34	0	45,260,046	34,203,476,823	0.0	5.0	1.0	5.0	0.0	0.0
35 to 49	0	23,308,004	17,433,696,263	0.0	---	---	---	---	---
50 to 64	0	17,791,341	14,896,503,318	0.0	30.0	1.0	30.0	0.0	0.0
65 to 79	0	5,972,512	5,341,542,875	0.0	---	---	---	---	---
80+	0	1,831,428	1,800,230,995	0.0	---	---	---	---	---
Chlorpropamide									
00 to 34	0	45,260,046	34,203,463,548	0.0	44.3	1.4	31.7	0.0	0.0
35 to 49	0	23,307,999	17,433,670,662	0.0	64.0	1.8	36.3	0.0	0.0
50 to 64	0	17,791,339	14,896,482,085	0.0	128.8	3.3	38.6	0.0	0.0
65 to 79	0	5,972,518	5,341,533,534	0.0	205.5	4.4	46.5	0.0	0.0
80+	0	1,831,421	1,800,215,895	0.0	213.6	4.0	53.9	0.0	0.0
Glimepiride									
00 to 34	105	45,260,124	34,203,071,018	0.1	65.1	2.0	32.3	3.8	13.9
35 to 49	1,846	23,308,368	17,432,184,556	0.8	79.9	2.4	33.5	3.2	11.8
50 to 64	5,835	17,792,450	14,894,112,976	1.8	107.7	2.9	36.6	2.4	8.9
65 to 79	12,068	5,973,987	5,340,369,138	3.3	159.2	3.6	44.2	3.7	13.4
80+	8,199	1,831,457	1,799,495,999	3.4	175.3	4.2	41.4	7.5	27.4
Glipizide									
00 to 34	1,515	45,260,177	34,202,631,499	0.2	83.1	1.9	44.8	7.5	27.3
35 to 49	13,440	23,308,355	17,430,029,496	1.6	107.9	2.4	45.7	4.5	16.3
50 to 64	49,161	17,792,348	14,890,329,521	3.7	144.0	3.0	48.4	3.8	13.9
65 to 79	101,107	5,974,704	5,337,209,227	7.3	211.4	3.8	55.7	4.4	16.0
80+	39,743	1,831,162	1,797,492,278	9.2	224.5	4.2	53.0	6.5	23.8

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1
Glipizide/Metformin										
00 to 34	296	296	659	23,828	25,010	68	2	0	2	0
35 to 49	1,431	1,431	3,752	138,558	144,672	396	1	0	1	0
50 to 64	1,812	1,812	5,851	228,795	234,031	641	6	0	6	0
65 to 79	621	621	1,992	92,771	93,991	257	6	2	4	207
80+	94	94	303	13,753	13,655	37	1	0	1	0
Glyburide										
00 to 34	23,334	23,334	41,011	1,517,774	1,622,688	4,443	49	19	30	606
35 to 49	31,031	31,031	66,472	2,729,494	2,798,124	7,661	115	27	88	2,278
50 to 64	35,355	35,355	97,851	4,335,231	4,324,936	11,841	166	71	95	6,757
65 to 79	22,493	22,493	75,860	3,773,916	3,741,342	10,243	198	72	126	8,216
80+	8,323	8,323	31,121	1,441,282	1,441,660	3,947	132	46	86	3,723
Glyburide/Metformin										
00 to 34	1,852	1,852	3,878	122,360	131,709	361	8	1	7	19
35 to 49	9,338	9,338	24,987	818,214	870,551	2,383	22	7	15	1,427
50 to 64	13,480	13,480	44,151	1,583,321	1,639,706	4,489	40	11	29	395
65 to 79	5,546	5,546	18,268	809,566	822,125	2,251	33	6	27	478
80+	865	865	2,980	126,936	128,053	351	10	4	6	602
Tolazamide										
00 to 34	297	297	498	38,333	35,404	97	0	0	0	0
35 to 49	1,699	1,699	3,468	291,613	277,085	759	3	2	1	600
50 to 64	3,050	3,050	7,797	674,652	648,522	1,776	17	8	9	1,419
65 to 79	2,211	2,211	5,978	521,713	504,535	1,381	25	22	3	4,155
80+	883	883	2,354	199,916	195,089	534	17	13	4	939

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Glipizide/Metformin									
00 to 34	251	45,260,047	34,203,449,457	0.0	80.5	2.2	36.2	8.0	29.2
35 to 49	31	23,307,993	17,433,584,315	0.1	96.8	2.6	36.9	0.7	2.5
50 to 64	798	17,791,334	14,896,362,867	0.1	126.3	3.2	39.1	2.6	9.4
65 to 79	277	5,972,523	5,341,509,826	0.1	149.4	3.2	46.6	6.4	23.3
80+	160	1,831,436	1,800,225,319	0.1	146.3	3.2	45.4	7.3	26.7
Glyburide									
00 to 34	722	45,260,169	34,197,034,303	0.5	65.0	1.8	37.0	3.0	11.0
35 to 49	5,949	23,304,677	17,424,530,912	1.3	88.0	2.1	41.1	4.1	15.0
50 to 64	9,547	17,792,151	14,892,224,649	2.0	122.6	2.8	44.3	3.8	14.0
65 to 79	18,378	5,974,313	5,339,081,477	3.8	167.8	3.4	49.7	5.3	19.3
80+	12,853	1,831,456	1,798,688,817	4.5	173.2	3.7	46.3	9.2	33.4
Glyburide/Metformin									
00 to 34	48	45,260,066	34,203,241,516	0.0	66.1	2.1	31.6	6.1	22.2
35 to 49	727	23,307,951	17,432,833,491	0.4	87.6	2.7	32.7	2.5	9.2
50 to 64	3,123	17,791,357	14,895,356,899	0.8	117.5	3.3	35.9	2.4	8.9
65 to 79	3,132	5,972,777	5,341,173,311	0.9	146.0	3.3	44.3	4.0	14.7
80+	306	1,831,446	1,800,133,234	0.5	146.7	3.4	42.6	7.8	28.5
Tolazamide									
00 to 34	0	45,260,057	34,203,426,358	0.0	129.1	1.7	77.0	0.0	0.0
35 to 49	1,932	23,308,094	17,433,427,926	0.1	171.6	2.0	84.1	1.1	4.0
50 to 64	2,202	17,791,613	14,896,012,536	0.2	221.2	2.6	86.5	2.6	9.6
65 to 79	1,206	5,972,935	5,341,224,158	0.4	236.0	2.7	87.3	5.0	18.1
80+	59	1,831,535	1,800,011,668	0.5	226.4	2.7	84.9	8.7	31.8

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1
Pioglitazone										
00 to 34	3,782	3,782	8,412	286,111	304,834	835	10	1	9	83
35 to 49	16,512	16,512	43,076	1,553,451	1,607,171	4,400	49	9	40	389
50 to 64	28,520	28,520	91,626	3,633,691	3,674,965	10,062	53	15	38	1,338
65 to 79	14,262	14,262	46,295	2,001,816	2,011,856	5,508	41	8	33	439
80+	3,258	3,258	11,102	443,313	450,859	1,234	16	5	11	274
Pioglitazone/Metformin										
00 to 34	1,398	1,398	2,867	94,619	103,044	282	3	0	3	0
35 to 49	6,921	6,921	17,313	594,425	637,932	1,747	6	0	6	0
50 to 64	9,085	9,085	27,713	1,049,160	1,095,112	2,998	5	1	4	68
65 to 79	2,539	2,539	7,376	307,632	319,230	874	3	2	1	17
80+	239	239	747	30,516	32,005	88	0	0	0	0
Rosiglitazone Maleate										
00 to 34	1,117	1,117	2,268	72,848	78,581	215	4	1	3	283
35 to 49	3,651	3,651	9,434	316,480	329,796	903	8	3	5	569
50 to 64	6,175	6,175	18,847	694,187	703,150	1,925	17	4	13	38
65 to 79	3,045	3,045	9,459	360,348	364,083	997	5	2	3	261
80+	792	792	2,466	91,937	93,495	256	2	0	2	0
Rosiglitazone/Metformin										
00 to 34	1,041	1,041	2,165	68,665	73,273	201	2	1	1	47
35 to 49	3,783	3,783	9,774	334,065	353,924	969	6	1	5	27
50 to 64	4,663	4,663	14,931	550,058	566,415	1,551	7	3	4	119
65 to 79	1,369	1,369	4,418	167,869	173,070	474	1	0	1	0
80+	138	138	352	14,045	14,966	41	0	0	0	0

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Pioglitazone									
00 to 34	52	45,260,152	34,202,576,559	0.1	75.7	2.2	34.0	3.3	12.0
35 to 49	1,253	23,308,592	17,431,603,789	0.7	94.1	2.6	36.1	3.0	11.1
50 to 64	8,864	17,793,448	14,893,515,060	1.6	127.4	3.2	39.7	1.4	5.3
65 to 79	9,226	5,974,918	5,340,193,849	2.4	140.4	3.2	43.2	2.0	7.4
80+	1,061	1,831,893	1,799,659,555	1.8	136.1	3.4	39.9	3.5	13.0
Pioglitazone/Metformin									
00 to 34	11	45,260,068	34,203,248,127	0.0	67.7	2.1	33.0	2.9	10.6
35 to 49	500	23,307,956	17,432,930,797	0.3	85.9	2.5	34.3	0.9	3.4
50 to 64	656	17,791,127	14,895,552,399	0.5	115.5	3.1	37.9	0.5	1.7
65 to 79	67	5,972,482	5,341,242,231	0.4	121.2	2.9	41.7	0.9	3.4
80+	0	1,831,412	1,800,190,142	0.1	127.7	3.1	40.9	0.0	0.0
Rosiglitazone Maleate									
00 to 34	130	45,260,099	34,203,137,307	0.0	65.2	2.0	32.1	5.1	18.6
35 to 49	62	23,308,123	17,432,922,370	0.2	86.7	2.6	33.5	2.4	8.9
50 to 64	579	17,791,961	14,895,600,842	0.3	112.4	3.1	36.8	2.4	8.8
65 to 79	28	5,972,969	5,341,194,811	0.5	118.3	3.1	38.1	1.4	5.0
80+	208	1,831,483	1,800,031,799	0.4	116.1	3.1	37.3	2.1	7.8
Rosiglitazone/Metformin									
00 to 34	18	45,260,066	34,203,162,074	0.0	66.0	2.1	31.7	2.7	10.0
35 to 49	19	23,307,889	17,432,968,237	0.2	88.3	2.6	34.2	1.7	6.2
50 to 64	232	17,791,119	14,895,701,077	0.3	118.0	3.2	36.8	1.2	4.5
65 to 79	74	5,972,507	5,341,362,758	0.2	122.6	3.2	38.0	0.6	2.1
80+	0	1,831,389	1,800,186,389	0.1	101.8	2.6	39.9	0.0	0.0

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	New Users	New Episodes	Dispensings	Total Days			New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
				Supplied	Days at Risk	Years at Risk					
Insulin (Rapid-Acting)											
Female	65,527	65,527	96,251	3,409,767	3,581,371	9,805	529	181	348	8,469	15,604
Male	59,759	59,759	90,126	3,268,179	3,389,386	9,280	505	150	355	6,348	16,572
Unknown	3	3	3	83	76	0	0	0	0	0	0
Insulin (Short-Acting)											
Female	0	0	0	0	0	0	0	0	0	0	0
Male	0	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0	0
Insulin (Long-Acting)											
Female	49,229	49,229	70,505	2,552,049	2,578,994	7,061	358	83	275	3,621	11,685
Male	57,649	57,649	83,614	3,053,491	3,078,375	8,428	359	103	256	5,493	12,851
Unknown	1	1	1	30	40	0	0	0	0	0	0
Insulin (Intermediate-Acting)											
Female	33,014	33,014	49,537	1,691,271	1,784,287	4,885	166	68	98	3,614	5,845
Male	19,565	19,565	32,241	1,181,513	1,224,178	3,352	187	56	131	3,069	6,447
Unknown	1	1	1	28	1	0	0	0	0	0	0
Insulin (Intermediate/Rapid-Acting)											
Female	5,834	5,834	10,218	365,132	388,226	1,063	72	20	52	1,099	2,374
Male	6,560	6,560	11,763	431,992	453,617	1,242	83	27	56	1,938	6,711
Unknown	0	0	0	0	0	0	0	0	0	0	0
Insulin (Intermediate/Short-Acting)											
Female	1	1	1	5	15	0	0	0	0	0	0
Male	1	1	1	30	40	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0	0

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Insulin (Rapid-Acting)								
Female	44,102,471	38,110,666,091	1.5	52.0	1.5	35.4	14.8	54.0
Male	42,324,535	35,544,843,278	1.4	54.7	1.5	36.3	14.9	54.4
Unknown	4,399	2,985,114	0.7	27.7	1.0	27.7	0.0	0.0
Insulin (Short-Acting)								
Female	44,098,520	38,121,044,239	0.0	---	---	---	---	---
Male	42,320,776	35,551,422,686	0.0	---	---	---	---	---
Unknown	4,399	2,985,897	0.0	---	---	---	---	---
Insulin (Long-Acting)								
Female	44,102,915	38,117,558,245	1.1	51.8	1.4	36.2	13.9	50.7
Male	42,325,386	35,547,507,759	1.4	53.0	1.5	36.5	11.7	42.6
Unknown	4,399	2,985,544	0.2	30.0	1.0	30.0	0.0	0.0
Insulin (Intermediate-Acting)								
Female	44,100,461	38,112,173,713	0.7	51.2	1.5	34.1	9.3	34.0
Male	42,322,450	35,549,046,460	0.5	60.4	1.6	36.6	15.3	55.8
Unknown	4,399	2,985,810	0.2	28.0	1.0	28.0	0.0	0.0
Insulin (Intermediate/Rapid-Acting)								
Female	44,099,095	38,120,273,395	0.1	62.6	1.8	35.7	18.5	67.7
Male	42,321,327	35,550,452,760	0.2	65.9	1.8	36.7	18.3	66.8
Unknown	4,399	2,985,897	0.0	---	---	---	---	---
Insulin (Intermediate/Short-Acting)								
Female	44,098,520	38,121,043,630	0.0	5.0	1.0	5.0	0.0	0.0
Male	42,320,776	35,551,420,747	0.0	30.0	1.0	30.0	0.0	0.0
Unknown	4,399	2,985,897	0.0	---	---	---	---	---

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	New Users	New Episodes	Dispensings	Total Days			New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
				Supplied	Days at Risk	Years at Risk					
Chlorpropamide											
Female	141	141	456	19,936	20,805	57	0	0	0	0	0
Male	115	115	388	17,880	18,102	50	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0	0
Glimepiride											
Female	35,515	35,515	107,004	4,105,564	4,133,011	11,316	200	62	138	7,784	16,971
Male	45,338	45,338	138,323	5,371,445	5,399,009	14,782	142	36	106	3,898	11,082
Unknown	7	7	11	315	407	1	0	0	0	0	0
Glipizide											
Female	72,635	72,635	228,636	11,486,047	11,287,056	30,902	535	169	366	30,915	88,561
Male	98,429	98,429	306,083	15,630,283	15,343,075	42,007	680	185	495	32,707	116,405
Unknown	6	6	20	950	967	3	0	0	0	0	0
Glipizide/Metformin											
Female	1,692	1,692	4,802	191,720	197,051	539	4	1	3	40	77
Male	2,561	2,561	7,754	305,955	314,268	860	12	1	11	167	1,440
Unknown	1	1	1	30	40	0	0	0	0	0	0
Glyburide											
Female	68,183	68,183	165,628	6,937,389	7,092,754	19,419	317	127	190	12,758	21,530
Male	52,346	52,346	146,668	6,859,528	6,835,167	18,714	343	108	235	8,822	25,919
Unknown	7	7	19	780	829	2	0	0	0	0	0
Glyburide/Metformin											
Female	12,483	12,483	36,023	1,317,550	1,367,643	3,744	51	11	40	559	2,664
Male	18,598	18,598	58,241	2,142,847	2,224,501	6,090	62	18	44	2,362	4,672
Unknown	0	0	0	0	0	0	0	0	0	0	0

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Chlorpropamide								
Female	44,098,530	38,120,994,172	0.0	141.4	3.2	43.7	0.0	0.0
Male	42,320,789	35,551,385,655	0.0	155.5	3.4	46.1	0.0	0.0
Unknown	4,399	2,985,897	0.0	---	---	---	---	---
Glimepiride								
Female	44,101,249	38,118,194,695	0.8	115.6	3.0	38.4	4.8	17.7
Male	42,323,973	35,548,053,655	1.1	118.5	3.1	38.8	2.6	9.6
Unknown	4,399	2,985,337	1.6	45.0	1.6	28.6	0.0	0.0
Glipizide								
Female	44,103,643	38,113,333,544	1.6	158.1	3.1	50.2	4.7	17.3
Male	42,326,538	35,541,374,205	2.3	158.8	3.1	51.1	4.4	16.2
Unknown	4,399	2,984,272	1.4	158.3	3.3	47.5	0.0	0.0
Glipizide/Metformin								
Female	44,098,594	38,120,909,628	0.0	113.3	2.8	39.9	2.0	7.4
Male	42,320,855	35,551,236,259	0.1	119.5	3.0	39.5	3.8	13.9
Unknown	4,399	2,985,897	0.2	30.0	1.0	30.0	0.0	0.0
Glyburide								
Female	44,102,393	38,103,812,968	1.5	101.7	2.4	41.9	4.5	16.3
Male	42,325,225	35,544,762,104	1.2	131.0	2.8	46.8	5.0	18.3
Unknown	4,399	2,985,086	1.6	111.4	2.7	41.1	0.0	0.0
Glyburide/Metformin								
Female	44,099,231	38,119,925,839	0.3	105.5	2.9	36.6	3.7	13.6
Male	42,321,603	35,549,826,715	0.4	115.2	3.1	36.8	2.8	10.2
Unknown	4,399	2,985,897	0.0	---	---	---	---	---

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	New Users	New Episodes	Dispensings	Total Days			New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
				Supplied	Days at Risk	Years at Risk					
Tolazamide											
Female	3,588	3,588	8,664	734,238	701,364	1,920	34	25	9	3,277	2,909
Male	4,549	4,549	11,419	990,889	958,178	2,623	28	20	8	3,836	2,490
Unknown	3	3	12	1,100	1,093	3	0	0	0	0	0
Pioglitazone											
Female	28,949	28,949	82,706	3,207,944	3,284,236	8,992	80	20	60	1,540	4,492
Male	37,383	37,383	117,798	4,710,158	4,765,149	13,046	89	18	71	983	15,964
Unknown	2	2	7	280	300	1	0	0	0	0	0
Pioglitazone/Metformin											
Female	7,736	7,736	20,129	746,099	790,586	2,165	7	3	4	85	80
Male	12,446	12,446	35,887	1,330,253	1,396,737	3,824	10	0	10	0	1,154
Unknown	0	0	0	0	0	0	0	0	0	0	0
Rosiglitazone Maleate											
Female	7,124	7,124	20,034	697,071	715,669	1,959	22	7	15	357	406
Male	7,655	7,655	22,438	838,669	853,363	2,336	14	3	11	794	601
Unknown	1	1	2	60	73	0	0	0	0	0	0
Rosiglitazone/Metformin											
Female	4,997	4,997	13,498	476,484	497,446	1,362	10	3	7	145	330
Male	5,996	5,996	18,140	658,158	684,124	1,873	6	2	4	48	13
Unknown	1	1	2	60	78	0	0	0	0	0	0

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Tolazamide								
Female	44,099,308	38,120,469,979	0.1	204.6	2.4	84.7	4.8	17.7
Male	42,321,608	35,550,647,291	0.1	217.8	2.5	86.8	2.9	10.7
Unknown	4,400	2,985,376	0.7	366.7	4.0	91.7	0.0	0.0
Pioglitazone								
Female	44,102,497	38,117,044,473	0.7	110.8	2.9	38.8	2.4	8.9
Male	42,325,772	35,547,519,159	0.9	126.0	3.2	40.0	1.9	6.8
Unknown	4,399	2,985,180	0.5	140.0	3.5	40.0	0.0	0.0
Pioglitazone/Metformin								
Female	44,098,811	38,120,032,530	0.2	96.4	2.6	37.1	0.9	3.2
Male	42,321,196	35,550,145,269	0.3	106.9	2.9	37.1	0.7	2.6
Unknown	4,399	2,985,897	0.0	---	---	---	---	---
Rosiglitazone Maleate								
Female	44,099,614	38,119,624,027	0.2	97.8	2.8	34.8	3.1	11.2
Male	42,322,039	35,550,277,328	0.2	109.6	2.9	37.4	1.6	6.0
Unknown	4,399	2,985,774	0.2	60.0	2.0	30.0	0.0	0.0
Rosiglitazone/Metformin								
Female	44,098,752	38,119,923,716	0.1	95.4	2.7	35.3	2.0	7.3
Male	42,321,067	35,550,471,461	0.1	109.8	3.0	36.3	0.9	3.2
Unknown	4,399	2,985,358	0.2	60.0	2.0	30.0	0.0	0.0

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
Insulin (Rapid-Acting)											
2004	5,323	5,323	7,716	233,500	250,853	687	51	24	27	840	957
2005	5,203	5,203	7,537	224,824	247,728	678	39	19	20	669	415
2006	6,935	6,935	11,282	412,018	427,165	1,170	55	29	26	942	2,752
2007	9,207	9,207	14,193	476,430	503,319	1,378	79	23	56	742	2,046
2008	17,587	17,587	26,476	942,400	997,290	2,730	160	53	107	3,847	4,248
2009	21,543	21,543	32,751	1,185,417	1,244,140	3,406	176	48	128	2,045	5,735
2010	19,919	19,919	30,052	1,095,758	1,141,015	3,124	152	42	110	1,736	5,644
2011	19,623	19,623	29,047	1,090,244	1,132,280	3,100	181	47	134	2,755	6,712
2012	19,949	19,949	27,326	1,017,438	1,027,043	2,812	141	46	95	1,241	3,667
Insulin (Short-Acting)											
2004	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0	0	0
2010	0	0	0	0	0	0	0	0	0	0	0
2011	0	0	0	0	0	0	0	0	0	0	0
2012	0	0	0	0	0	0	0	0	0	0	0
Insulin (Long-Acting)											
2004	1,727	1,727	2,726	81,816	84,781	232	15	5	10	176	2,699
2005	1,890	1,890	2,922	90,766	93,064	255	13	6	7	165	292
2006	3,919	3,919	5,869	206,301	209,561	574	18	7	11	188	1,051
2007	6,186	6,186	9,258	319,830	327,129	896	54	14	40	648	1,767

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Eligible Members	Member-Days	New Users/ 1000 Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/ 1000 Years at Risk
Insulin (Rapid-Acting)								
2004	8,149,773	2,403,407,976	0.7	43.9	1.4	30.3	20.3	74.3
2005	8,382,114	2,530,844,610	0.6	43.2	1.4	29.8	15.7	57.5
2006	18,987,646	4,227,483,472	0.4	59.4	1.6	36.5	12.9	47.0
2007	22,540,550	6,016,000,674	0.4	51.7	1.5	33.6	15.7	57.3
2008	43,037,674	9,886,037,558	0.4	53.6	1.5	35.6	16.0	58.6
2009	44,862,835	12,703,194,392	0.5	55.0	1.5	36.2	14.1	51.7
2010	43,072,494	12,250,240,225	0.5	55.0	1.5	36.5	13.3	48.7
2011	41,912,376	12,038,490,336	0.5	55.6	1.5	37.5	16.0	58.4
2012	40,784,543	11,602,795,240	0.5	51.0	1.4	37.2	13.7	50.1
Insulin (Short-Acting)								
2004	8,149,455	2,403,402,962	0.0	---	---	---	---	---
2005	8,383,663	2,531,199,444	0.0	---	---	---	---	---
2006	18,989,957	4,228,055,659	0.0	---	---	---	---	---
2007	22,544,462	6,016,938,341	0.0	---	---	---	---	---
2008	43,043,631	9,887,578,956	0.0	---	---	---	---	---
2009	44,872,291	12,705,505,876	0.0	---	---	---	---	---
2010	43,085,853	12,253,452,517	0.0	---	---	---	---	---
2011	41,927,785	12,042,302,178	0.0	---	---	---	---	---
2012	40,801,883	11,607,016,889	0.0	---	---	---	---	---
Insulin (Long-Acting)								
2004	8,149,585	2,403,410,386	0.2	47.4	1.6	30.0	17.7	64.6
2005	8,383,430	2,531,142,244	0.2	48.0	1.5	31.1	14.0	51.0
2006	18,989,765	4,227,974,767	0.2	52.6	1.5	35.2	8.6	31.4
2007	22,543,585	6,016,744,649	0.3	51.7	1.5	34.5	16.5	60.3

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
Insulin (Long-Acting) Continued											
2008	14,375	14,375	20,942	733,377	759,773	2,080	93	25	68	2,616	3,086
2009	19,424	19,424	28,521	1,018,611	1,037,476	2,840	139	35	104	1,445	5,089
2010	18,695	18,695	27,378	1,004,005	1,023,276	2,802	124	28	96	881	3,172
2011	19,363	19,363	28,017	1,058,527	1,061,015	2,905	141	26	115	1,335	4,877
2012	21,300	21,300	28,487	1,092,337	1,061,334	2,906	120	40	80	1,660	2,503
Insulin (Intermediate-Acting)											
2004	3,859	3,859	5,931	192,411	205,912	564	37	16	21	364	740
2005	3,219	3,219	4,839	163,453	173,976	476	25	10	15	412	338
2006	4,253	4,253	7,073	248,814	261,055	715	25	14	11	426	707
2007	4,883	4,883	7,582	260,536	274,837	752	26	10	16	458	1,598
2008	7,233	7,233	11,542	399,912	423,808	1,160	57	18	39	1,016	2,598
2009	8,007	8,007	12,604	434,818	458,332	1,255	48	19	29	2,125	1,602
2010	7,081	7,081	11,442	409,201	427,678	1,171	39	8	31	223	1,712
2011	6,910	6,910	10,597	387,310	400,309	1,096	46	15	31	1,037	1,910
2012	7,135	7,135	10,169	376,357	382,559	1,047	50	14	36	622	1,087
Insulin (Intermediate/Rapid-Acting)											
2004	1,348	1,348	2,672	87,319	91,653	251	20	8	12	921	3,251
2005	1,057	1,057	1,813	60,889	65,486	179	18	4	14	31	257
2006	1,085	1,085	2,212	78,823	82,711	226	8	4	4	146	548
2007	1,196	1,196	2,028	75,749	80,605	221	19	11	8	918	512
2008	1,899	1,899	3,449	122,249	130,729	358	21	6	15	434	1,147
2009	2,030	2,030	3,549	130,846	138,074	378	24	5	19	94	697
2010	1,500	1,500	2,683	98,750	104,490	286	21	2	19	134	2,048
2011	1,136	1,136	1,922	76,172	80,668	221	7	1	6	35	94
2012	1,143	1,143	1,653	66,327	67,427	185	17	6	11	324	531

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Eligible Members	Member-Days	New Users/ 1000 Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/ 1000 Years at Risk
Insulin (Long-Acting) Continued								
2008	43,041,830	9,887,089,069	0.3	51.0	1.5	35.0	12.2	44.7
2009	44,868,271	12,704,568,146	0.4	52.4	1.5	35.7	13.4	48.9
2010	43,079,111	12,251,931,260	0.4	53.7	1.5	36.7	12.1	44.3
2011	41,919,773	12,040,432,748	0.5	54.7	1.4	37.8	13.3	48.5
2012	40,792,131	11,604,758,279	0.5	51.3	1.3	38.3	11.3	41.3
Insulin (Intermediate-Acting)								
2004	8,149,930	2,403,442,165	0.5	49.9	1.5	32.4	18.0	65.6
2005	8,382,619	2,530,967,550	0.4	50.8	1.5	33.8	14.4	52.5
2006	18,987,963	4,227,563,041	0.2	58.5	1.7	35.2	9.6	35.0
2007	22,541,358	6,016,206,241	0.2	53.4	1.6	34.4	9.5	34.6
2008	43,039,054	9,886,440,838	0.2	55.3	1.6	34.6	13.4	49.1
2009	44,865,870	12,703,927,190	0.2	54.3	1.6	34.5	10.5	38.3
2010	43,077,372	12,251,355,023	0.2	57.8	1.6	35.8	9.1	33.3
2011	41,918,417	12,039,890,745	0.2	56.1	1.5	36.5	11.5	42.0
2012	40,791,736	11,604,413,190	0.2	52.7	1.4	37.0	13.1	47.7
Insulin (Intermediate/Rapid-Acting)								
2004	8,149,580	2,403,417,305	0.2	64.8	2.0	32.7	21.8	79.7
2005	8,383,392	2,531,148,646	0.1	57.6	1.7	33.6	27.5	100.4
2006	18,989,541	4,227,973,667	0.1	72.6	2.0	35.6	9.7	35.3
2007	22,543,820	6,016,811,601	0.1	63.3	1.7	37.4	23.6	86.1
2008	43,042,742	9,887,387,614	0.0	64.4	1.8	35.4	16.1	58.7
2009	44,870,977	12,705,239,206	0.0	64.5	1.7	36.9	17.4	63.5
2010	43,084,283	12,253,125,197	0.0	65.8	1.8	36.8	20.1	73.4
2011	41,926,174	12,041,949,154	0.0	67.1	1.7	39.6	8.7	31.7
2012	40,800,246	11,606,659,662	0.0	58.0	1.4	40.1	25.2	92.1

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
Insulin (Intermediate/Short-Acting)											
2004	1	1	1	30	40	0	0	0	0	0	0
2005	1	1	1	5	15	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0	0	0
2010	0	0	0	0	0	0	0	0	0	0	0
2011	0	0	0	0	0	0	0	0	0	0	0
2012	0	0	0	0	0	0	0	0	0	0	0
Chlorpropamide											
2004	51	51	159	5,589	5,891	16	0	0	0	0	0
2005	25	25	33	1,220	1,354	4	0	0	0	0	0
2006	34	34	162	8,292	8,460	23	0	0	0	0	0
2007	30	30	216	10,014	9,973	27	0	0	0	0	0
2008	35	35	67	2,577	2,780	8	0	0	0	0	0
2009	29	29	94	4,224	4,381	12	0	0	0	0	0
2010	24	24	61	3,330	3,504	10	0	0	0	0	0
2011	15	15	37	2,050	1,957	5	0	0	0	0	0
2012	13	13	15	520	607	2	0	0	0	0	0
Glimepiride											
2004	1,703	1,703	7,639	232,948	236,446	647	24	10	14	1,504	937
2005	1,115	1,115	3,751	122,449	125,708	344	11	6	5	958	238
2006	2,646	2,646	10,144	390,542	392,176	1,074	9	2	7	492	919
2007	4,815	4,815	19,603	727,246	736,330	2,016	22	5	17	362	3,356
2008	10,955	10,955	37,000	1,397,589	1,417,470	3,881	64	22	42	4,231	6,771
2009	15,491	15,491	49,103	1,880,270	1,902,631	5,209	73	17	56	1,028	6,550
2010	14,678	14,678	45,362	1,777,508	1,800,136	4,929	62	19	43	1,780	5,893
2011	14,592	14,592	41,344	1,682,715	1,685,969	4,616	39	5	34	582	1,964
2012	14,865	14,865	31,392	1,266,057	1,235,561	3,383	38	12	26	745	1,425

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Eligible Members	Member-Days	New Users/ 1000 Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1000 Years at Risk
Insulin (Intermediate/Short-Acting)								
2004	8,149,455	2,403,402,987	0.0	30.0	1.0	30.0	0.0	0.0
2005	8,383,662	2,531,199,108	0.0	5.0	1.0	5.0	0.0	0.0
2006	18,989,955	4,228,055,171	0.0	---	---	---	---	---
2007	22,544,460	6,016,937,889	0.0	---	---	---	---	---
2008	43,043,629	9,887,578,313	0.0	---	---	---	---	---
2009	44,872,290	12,705,505,511	0.0	---	---	---	---	---
2010	43,085,851	12,253,452,228	0.0	---	---	---	---	---
2011	41,927,785	12,042,302,178	0.0	---	---	---	---	---
2012	40,801,883	11,607,016,889	0.0	---	---	---	---	---
Chlorpropamide								
2004	8,149,456	2,403,403,111	0.0	109.6	3.1	35.2	0.0	0.0
2005	8,383,643	2,531,194,446	0.0	48.8	1.3	37.0	0.0	0.0
2006	18,989,944	4,228,051,879	0.0	243.9	4.8	51.2	0.0	0.0
2007	22,544,445	6,016,932,346	0.0	333.8	7.2	46.4	0.0	0.0
2008	43,043,601	9,887,570,040	0.0	73.6	1.9	38.5	0.0	0.0
2009	44,872,237	12,705,492,569	0.0	145.7	3.2	44.9	0.0	0.0
2010	43,085,799	12,253,435,353	0.0	138.8	2.5	54.6	0.0	0.0
2011	41,927,728	12,042,285,604	0.0	136.7	2.5	55.4	0.0	0.0
2012	40,801,829	11,607,000,376	0.0	40.0	1.2	34.7	0.0	0.0
Glimepiride								
2004	8,149,556	2,403,410,684	0.2	136.8	4.5	30.5	10.2	37.1
2005	8,383,402	2,531,144,935	0.1	109.8	3.4	32.6	8.8	32.0
2006	18,989,822	4,227,999,515	0.1	147.6	3.8	38.5	2.3	8.4
2007	22,543,844	6,016,790,901	0.2	151.0	4.1	37.1	3.0	10.9
2008	43,042,199	9,887,204,219	0.3	127.6	3.4	37.8	4.5	16.5
2009	44,869,142	12,704,804,739	0.3	121.4	3.2	38.3	3.8	14.0
2010	43,080,026	12,252,208,796	0.3	121.1	3.1	39.2	3.4	12.6
2011	41,920,437	12,040,641,937	0.3	115.3	2.8	40.7	2.3	8.4
2012	40,793,084	11,605,027,961	0.4	85.2	2.1	40.3	3.1	11.2

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
Glipizide											
2004	5,778	5,778	26,333	1,351,907	1,329,975	3,641	46	19	27	6,954	14,034
2005	6,382	6,382	26,750	1,556,251	1,530,190	4,189	51	22	29	2,535	10,904
2006	11,436	11,436	47,489	2,590,978	2,546,234	6,971	83	42	41	10,859	29,089
2007	15,953	15,953	60,578	3,446,554	3,385,145	9,268	115	41	74	14,283	40,385
2008	24,577	24,577	83,643	4,042,695	4,012,665	10,986	143	33	110	7,028	29,126
2009	29,257	29,257	93,632	4,452,346	4,417,822	12,095	208	68	140	8,392	32,900
2010	26,873	26,873	79,875	3,914,319	3,862,919	10,576	191	45	146	8,187	24,220
2011	25,820	25,820	67,629	3,388,895	3,330,056	9,117	211	44	167	3,943	19,517
2012	24,994	24,994	48,810	2,373,335	2,216,092	6,067	167	40	127	1,441	4,791
Glipizide/Metformin											
2004	26	26	40	1,459	1,542	4	0	0	0	0	0
2005	17	17	52	1,632	1,600	4	0	0	0	0	0
2006	128	128	581	22,087	22,798	62	1	0	1	0	56
2007	252	252	932	37,910	38,933	107	0	0	0	0	0
2008	631	631	1,999	81,377	83,785	229	2	0	2	0	2
2009	878	878	2,892	113,270	117,361	321	1	0	1	0	20
2010	794	794	2,327	92,697	95,540	262	2	1	1	167	230
2011	779	779	2,186	86,265	88,194	241	3	0	3	0	523
2012	749	749	1,548	61,008	61,606	169	7	1	6	40	686
Glyburide											
2004	11,362	11,362	36,548	1,973,046	1,956,403	5,356	88	36	52	5,115	11,538
2005	9,782	9,782	26,674	1,497,004	1,486,208	4,069	65	37	28	4,954	4,187
2006	9,808	9,808	29,813	1,484,849	1,473,681	4,035	48	24	24	3,407	1,693
2007	9,269	9,269	26,737	1,154,127	1,168,008	3,198	48	14	34	599	6,079

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Eligible Members	Member-Days	New Users/ 1000 Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1000 Years at Risk
Glipizide								
2004	8,149,981	2,403,468,321	0.7	234.0	4.6	51.3	3.5	12.6
2005	8,382,889	2,531,057,821	0.8	243.9	4.2	58.2	3.3	12.2
2006	18,988,196	4,227,657,166	0.6	226.6	4.2	54.6	3.3	11.9
2007	22,540,890	6,016,136,150	0.7	216.0	3.8	56.9	3.4	12.4
2008	43,036,986	9,886,014,322	0.6	164.5	3.4	48.3	3.6	13.0
2009	44,861,407	12,703,050,349	0.7	152.2	3.2	47.6	4.7	17.2
2010	43,070,338	12,249,998,668	0.6	145.7	3.0	49.0	4.9	18.1
2011	41,909,366	12,038,079,023	0.6	131.3	2.6	50.1	6.3	23.1
2012	40,781,004	11,602,230,201	0.6	95.0	2.0	48.6	7.5	27.5
Glipizide/Metformin								
2004	8,149,457	2,403,402,994	0.0	56.1	1.5	36.5	0.0	0.0
2005	8,383,658	2,531,197,492	0.0	96.0	3.1	31.4	0.0	0.0
2006	18,989,952	4,228,053,083	0.0	172.6	4.5	38.0	4.4	16.0
2007	22,544,431	6,016,932,717	0.0	150.4	3.7	40.7	0.0	0.0
2008	43,043,561	9,887,563,961	0.0	129.0	3.2	40.7	2.4	8.7
2009	44,872,100	12,705,470,751	0.0	129.0	3.3	39.2	0.9	3.1
2010	43,085,509	12,253,389,655	0.0	116.7	2.9	39.8	2.1	7.6
2011	41,927,317	12,042,208,257	0.0	110.7	2.8	39.5	3.4	12.4
2012	40,801,351	11,606,912,874	0.0	81.5	2.1	39.4	11.4	41.5
Glyburide								
2004	8,150,604	2,403,559,362	1.4	173.7	3.2	54.0	4.5	16.4
2005	8,381,546	2,530,777,039	1.2	153.0	2.7	56.1	4.4	16.0
2006	18,985,795	4,227,143,690	0.5	151.4	3.0	49.8	3.3	11.9
2007	22,538,129	6,015,483,377	0.4	124.5	2.9	43.2	4.1	15.0

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
Glyburide continued											
2008	14,908	14,908	40,591	1,609,271	1,649,884	4,517	94	28	66	1,374	9,705
2009	18,666	18,666	46,955	1,875,793	1,927,586	5,277	101	35	66	2,455	6,317
2010	16,967	16,967	42,586	1,726,717	1,767,372	4,839	75	24	51	1,249	2,816
2011	15,219	15,219	35,357	1,413,691	1,446,319	3,960	83	22	61	1,685	3,058
2012	14,555	14,555	27,054	1,063,199	1,053,289	2,884	58	15	43	742	2,056
Glyburide/Metformin											
2004	549	549	1,798	59,017	59,968	164	4	2	2	36	50
2005	379	379	1,421	49,860	51,015	140	2	1	1	3	729
2006	1,571	1,571	6,439	243,952	248,583	681	5	2	3	607	646
2007	2,457	2,457	9,171	327,904	339,270	929	9	4	5	383	631
2008	5,491	5,491	17,800	645,038	673,969	1,845	19	4	15	865	1,470
2009	6,917	6,917	21,517	775,235	811,605	2,222	24	3	21	347	2,092
2010	5,383	5,383	16,175	594,067	620,217	1,698	23	5	18	80	891
2011	4,411	4,411	11,990	455,706	473,989	1,298	8	1	7	45	127
2012	3,923	3,923	7,953	309,618	313,528	858	19	7	12	555	700
Tolazamide											
2004	3,262	3,262	9,028	800,861	770,948	2,111	28	19	9	4,471	3,306
2005	2,423	2,423	6,485	570,289	551,004	1,509	21	17	4	1,998	1,988
2006	1,305	1,305	2,769	234,667	223,545	612	10	7	3	583	30
2007	324	324	495	43,099	40,390	111	0	0	0	0	0
2008	175	175	322	25,869	24,491	67	2	2	0	61	0
2009	97	97	158	12,297	12,188	33	0	0	0	0	0
2010	57	57	130	8,830	8,596	24	1	0	1	0	75
2011	40	40	93	6,257	6,179	17	0	0	0	0	0
2012	457	457	615	24,058	23,294	64	0	0	0	0	0

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Eligible Members	Member-Days	New Users/ 1000 Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1000 Years at Risk
Glyburide continued								
2008	43,034,707	9,885,368,622	0.3	107.9	2.7	39.6	5.7	20.8
2009	44,859,562	12,702,363,395	0.4	100.5	2.5	39.9	5.2	19.1
2010	43,068,225	12,248,992,322	0.4	101.8	2.5	40.5	4.2	15.5
2011	41,907,061	12,036,886,764	0.4	92.9	2.3	40.0	5.7	21.0
2012	40,778,839	11,600,985,587	0.4	73.0	1.9	39.3	5.5	20.1
Glyburide/Metformin								
2004	8,149,521	2,403,408,225	0.1	107.5	3.3	32.8	6.7	24.4
2005	8,383,548	2,531,176,757	0.0	131.6	3.7	35.1	3.9	14.3
2006	18,989,907	4,228,036,569	0.1	155.3	4.1	37.9	2.0	7.3
2007	22,544,127	6,016,869,151	0.1	133.5	3.7	35.8	2.7	9.7
2008	43,042,777	9,887,392,131	0.1	117.5	3.2	36.2	2.8	10.3
2009	44,870,389	12,705,143,503	0.2	112.1	3.1	36.0	3.0	10.8
2010	43,082,801	12,252,864,918	0.1	110.4	3.0	36.7	3.7	13.5
2011	41,924,269	12,041,592,970	0.1	103.3	2.7	38.0	1.7	6.2
2012	40,798,128	11,606,254,227	0.1	78.9	2.0	38.9	6.1	22.1
Tolazamide								
2004	8,149,958	2,403,476,270	0.4	245.5	2.8	88.7	3.6	13.3
2005	8,383,309	2,531,148,315	0.3	235.4	2.7	87.9	3.8	13.9
2006	18,989,090	4,227,880,459	0.1	179.8	2.1	84.7	4.5	16.3
2007	22,543,432	6,016,732,015	0.0	133.0	1.5	87.1	0.0	0.0
2008	43,042,634	9,887,358,387	0.0	147.8	1.8	80.3	8.2	29.8
2009	44,871,375	12,705,292,878	0.0	126.8	1.6	77.8	0.0	0.0
2010	43,085,062	12,253,251,388	0.0	154.9	2.3	67.9	11.6	42.5
2011	41,927,066	12,042,122,568	0.0	156.4	2.3	67.3	0.0	0.0
2012	40,801,191	11,606,840,366	0.0	52.6	1.3	39.1	0.0	0.0

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
Pioglitazone											
2004	2,787	2,787	12,257	432,909	437,495	1,198	9	3	6	54	118
2005	2,415	2,415	7,279	293,089	297,367	814	7	3	4	256	43
2006	5,360	5,360	22,320	932,451	937,674	2,567	19	6	13	515	6,543
2007	6,807	6,807	24,884	1,012,632	1,031,412	2,824	19	4	15	464	4,308
2008	11,755	11,755	36,309	1,405,173	1,438,616	3,939	30	5	25	95	3,739
2009	14,112	14,112	41,630	1,620,340	1,655,935	4,534	39	9	30	676	3,795
2010	11,474	11,474	30,925	1,209,480	1,236,208	3,385	17	5	12	196	485
2011	7,266	7,266	16,714	674,739	683,730	1,872	18	3	15	267	408
2012	4,358	4,358	8,193	337,569	331,248	907	11	0	11	0	1,017
Pioglitazone/Metformin											
2004	0	0	0	0	0	0	0	0	0	0	0
2005	14	14	26	780	812	2	0	0	0	0	0
2006	1,129	1,129	4,395	170,640	175,492	480	0	0	0	0	0
2007	1,895	1,895	6,355	238,112	250,831	687	3	2	1	17	99
2008	4,133	4,133	11,943	433,024	458,606	1,256	3	0	3	0	964
2009	5,461	5,461	15,348	558,098	591,314	1,619	4	1	3	68	73
2010	4,013	4,013	10,582	391,919	413,243	1,131	4	0	4	0	77
2011	2,330	2,330	5,093	195,332	205,605	563	2	0	2	0	17
2012	1,207	1,207	2,274	88,447	91,420	250	1	0	1	0	4
Rosiglitazone Maleate											
2004	2,210	2,210	9,977	303,649	311,250	852	15	6	9	1,095	265
2005	1,557	1,557	4,495	143,751	148,042	405	5	1	4	2	160
2006	2,896	2,896	8,734	342,833	341,732	936	4	0	4	0	30
2007	2,545	2,545	6,348	248,130	251,552	689	1	0	1	0	202
2008	2,278	2,278	5,626	219,833	228,746	626	4	1	3	13	188
2009	2,197	2,197	5,136	193,566	200,413	549	4	1	3	30	144
2010	961	961	1,912	73,299	76,410	209	3	1	2	11	18
2011	127	127	213	8,969	9,212	25	0	0	0	0	0
2012	9	9	33	1,770	1,748	5	0	0	0	0	0

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Eligible Members	Member-Days	New Users/ 1000 Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1000 Years at Risk
Pioglitazone								
2004	8,149,987	2,403,473,509	0.3	155.3	4.4	35.3	2.1	7.5
2005	8,383,583	2,531,171,483	0.3	121.4	3.0	40.3	2.4	8.6
2006	18,989,947	4,227,993,484	0.3	174.0	4.2	41.8	2.0	7.4
2007	22,543,351	6,016,678,661	0.3	148.8	3.7	40.7	1.8	6.7
2008	43,040,993	9,886,888,264	0.3	119.5	3.1	38.7	2.1	7.6
2009	44,867,549	12,704,369,148	0.3	114.8	2.9	38.9	2.4	8.6
2010	43,078,885	12,251,767,159	0.3	105.4	2.7	39.1	1.4	5.0
2011	41,920,065	12,040,332,761	0.2	92.9	2.3	40.4	2.6	9.6
2012	40,793,539	11,604,874,343	0.1	77.5	1.9	41.2	3.3	12.1
Pioglitazone/Metformin								
2004	8,149,455	2,403,402,962	0.0	---	---	---	---	---
2005	8,383,663	2,531,199,444	0.0	55.7	1.9	30.0	0.0	0.0
2006	18,989,964	4,228,054,556	0.1	151.1	3.9	38.8	0.0	0.0
2007	22,544,235	6,016,897,563	0.1	125.7	3.4	37.5	1.2	4.4
2008	43,042,965	9,887,439,441	0.1	104.8	2.9	36.3	0.7	2.4
2009	44,870,752	12,705,211,246	0.1	102.2	2.8	36.4	0.7	2.5
2010	43,083,198	12,252,947,628	0.1	97.7	2.6	37.0	1.0	3.5
2011	41,924,664	12,041,668,294	0.1	83.8	2.2	38.4	1.0	3.6
2012	40,798,772	11,606,342,562	0.0	73.3	1.9	38.9	1.1	4.0
Rosiglitazone Maleate								
2004	8,149,672	2,403,426,166	0.3	137.4	4.5	30.4	4.8	17.6
2005	8,383,408	2,531,142,214	0.2	92.3	2.9	32.0	3.4	12.3
2006	18,989,829	4,227,996,605	0.2	118.4	3.0	39.3	1.2	4.3
2007	22,543,712	6,016,771,132	0.1	97.5	2.5	39.1	0.4	1.5
2008	43,042,001	9,887,160,414	0.1	96.5	2.5	39.1	1.7	6.4
2009	44,870,433	12,705,049,052	0.0	88.1	2.3	37.7	2.0	7.3
2010	43,083,863	12,252,958,738	0.0	76.3	2.0	38.3	3.9	14.3
2011	41,925,863	12,041,801,406	0.0	70.6	1.7	42.1	0.0	0.0
2012	40,800,238	11,606,581,402	0.0	196.7	3.7	53.6	0.0	0.0

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2
Rosiglitazone/Metformin											
2004	1,691	1,691	6,061	181,864	187,685	514	7	4	3	192	251
2005	617	617	984	30,376	31,253	86	1	0	1	0	1
2006	1,435	1,435	5,234	207,559	211,618	579	3	0	3	0	12
2007	1,736	1,736	5,930	220,052	226,604	620	3	1	2	1	20
2008	2,204	2,204	5,847	212,990	226,387	620	0	0	0	0	0
2009	2,205	2,205	5,468	198,423	209,852	575	0	0	0	0	0
2010	970	970	1,873	73,342	77,785	213	1	0	1	0	58
2011	134	134	240	9,915	10,263	28	1	0	1	0	1
2012	2	2	3	181	201	1	0	0	0	0	0

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Eligible Members	Member-Days	New Users/ 1000 Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1000 Years at Risk
Rosiglitazone/Metformin								
2004	8,149,469	2,403,398,763	0.2	107.5	3.6	30.0	3.7	13.6
2005	8,383,329	2,531,134,857	0.1	49.2	1.6	30.9	3.2	11.7
2006	18,989,585	4,227,979,528	0.1	144.6	3.6	39.7	1.4	5.2
2007	22,543,737	6,016,775,310	0.1	126.8	3.4	37.1	1.3	4.8
2008	43,042,433	9,887,295,296	0.1	96.6	2.7	36.4	0.0	0.0
2009	44,870,692	12,705,174,621	0.0	90.0	2.5	36.3	0.0	0.0
2010	43,084,063	12,253,067,997	0.0	75.6	1.9	39.2	1.3	4.7
2011	41,925,999	12,041,906,548	0.0	74.0	1.8	41.3	9.7	35.6
2012	40,800,293	11,606,647,615	0.0	90.5	1.5	60.3	0.0	0.0