

## 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 MSY4\_MPR38\_V1**

<b><u>Request Description</u></b>	This request investigates incident use of nine selective serotonin reuptake inhibitor (SSRI) antidepressant medications in the Mini-Sentinel Distributed Database (MSDD). Modular Program 3 was run twice. The results of the first run are presented in this report. The second report presents incidence of each drug with respect to all specified SSRI antidepressants. A user was considered a new user if he/she was not exposed to the drug product of interest in the prior 183 days. The time period for the request is January 1, 2000 – December 31, 2011. The package was distributed to 18 Data Partners on June 10, 2013.
<b><u>Request ID</u></b>	msy4_mpr38_v1
<b><u>Glossary</u></b>	Glossary of Terms in Modular Program 3
<b><u>Table 1</u></b>	Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2011, by Drug Product
<b><u>Table 2</u></b>	Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2011, by Drug Product and Age Group
<b><u>Table 3</u></b>	Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2011, by Drug Product and Sex
<b><u>Table 4</u></b>	Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2011, by Drug Product and Year
<b><u>Appendix A</u></b>	Available Data in the Mini-Sentinel Distributed Database (MSDD) for Each Data Partner as of Request Send Date (June 10, 2013)
<b><u>Appendix B</u></b>	Specifications for Request MSY4_MPR38_V1
<b><u>Notes:</u></b>	<p>Please refer to the Sentinel Distributed Query Tool Summary Table documentation and Investigator manual on the Sentinel website (<a href="https://www.sentinelinitiative.org/sentinel/routine-querying-tools/summary-table-queries">https://www.sentinelinitiative.org/sentinel/routine-querying-tools/summary-table-queries</a>) for more details.</p> <p>Please contact the Sentinel Operations Center Query Fulfillment Team (<a href="mailto:qf@sentinelssystem.org">qf@sentinelssystem.org</a>) for questions and to provide comments/suggestions for future enhancements to this document.</p>

### **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 incidence 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 incidence 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.

**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.

\*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 Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product**

	New Users	New Episodes	Dispensings	Total Days at		Eligible Members	Eligible Member-Days	New Users/ 1K		Average Days Dispensings/ User	Average Days Supplied/ Dispensing
				Risk	Days at Risk			Eligible Members	Average Days Supplied/ User		
<b>Citalopram</b>	1,743,217	1,743,217	5,752,460	222,549,590	223,313,290	83,259,181	72,216,466,028	20.94	127.67	3.30	38.69
<b>Desvenlafaxine</b>	167,429	167,429	672,118	22,379,195	22,625,159	83,654,599	73,701,829,932	2.00	133.66	4.01	33.30
<b>Duloxetine</b>	593,164	593,164	2,217,150	77,165,431	77,674,464	83,462,772	73,251,304,630	7.11	130.09	3.74	34.80
<b>Escitalopram</b>	1,121,864	1,121,864	3,844,704	130,653,728	131,889,101	83,236,352	72,583,340,490	13.48	116.46	3.43	33.98
<b>Fluoxetine</b>	816,503	816,503	2,762,468	108,026,992	108,381,894	83,341,729	72,488,870,406	9.80	132.30	3.38	39.11
<b>Paroxetine</b>	1,566,986	1,566,986	5,438,567	195,808,951	196,812,093	83,012,774	72,005,204,620	18.88	124.96	3.47	36.00
<b>Sertraline</b>	1,529,646	1,529,646	5,253,537	232,807,239	233,052,968	83,196,523	71,642,124,499	18.39	152.20	3.43	44.31
<b>Venlafaxine</b>	687,362	687,362	2,864,910	103,115,720	103,676,841	83,315,954	72,848,523,205	8.25	150.02	4.17	35.99
<b>Vilazodone</b>	9,720	9,720	16,068	520,556	515,268	83,682,052	73,792,481,580	0.12	53.56	1.65	32.40

**Table 2. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Age Group**

	New Users	New Episodes	Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K Eligible Members	Average Days Supplied/ User	Average Dispensings/ User	Average Days Supplied/ Dispensing
<b>Citalopram</b>											
0 to 41 years	733,735	733,735	2,086,048	74,049,489	74,457,834	50,833,899	39,207,948,031	14.43	100.92	2.84	35.50
41 to 55 years	496,446	496,446	1,716,754	66,108,710	66,446,125	20,850,500	16,318,073,187	23.81	133.16	3.46	38.51
55 to 65 years	256,528	256,528	942,281	39,148,397	39,191,730	11,168,506	8,962,174,034	22.97	152.61	3.67	41.55
65 to 75 years	128,330	128,330	480,125	21,561,801	21,585,440	5,192,819	4,429,833,740	24.71	168.02	3.74	44.91
75 to 85 years	88,750	88,750	352,963	15,046,652	15,043,442	2,582,561	2,453,418,558	34.37	169.54	3.98	42.63
85+ years	39,428	39,428	174,289	6,634,541	6,588,719	978,752	845,018,478	40.28	168.27	4.42	38.07
<b>Desvenlafaxine</b>											
0 to 41 years	68,479	68,479	247,594	7,845,794	7,954,004	50,973,239	39,725,802,838	1.34	114.57	3.62	31.69
41 to 55 years	63,453	63,453	271,876	9,078,808	9,187,520	21,063,268	16,768,263,091	3.01	143.08	4.28	33.39
55 to 65 years	27,523	27,523	122,768	4,343,139	4,367,493	11,331,484	9,232,698,582	2.43	157.80	4.46	35.38
65 to 75 years	5,601	5,601	20,958	787,641	790,546	5,270,643	4,558,275,600	1.06	140.63	3.74	37.58
75 to 85 years	1,920	1,920	7,039	260,126	261,285	2,624,909	2,535,612,416	0.73	135.48	3.67	36.95
85+ years	453	453	1,883	63,687	64,311	1,002,682	881,177,405	0.45	140.59	4.16	33.82
<b>Duloxetine</b>											
0 to 41 years	190,414	190,414	619,159	20,075,926	20,263,738	50,923,849	39,618,597,183	3.74	105.43	3.25	32.42
41 to 55 years	214,376	214,376	846,633	29,313,956	29,536,851	20,958,976	16,602,641,064	10.23	136.74	3.95	34.62
55 to 65 years	117,351	117,351	486,231	17,982,773	18,042,661	11,248,660	9,120,938,367	10.43	153.24	4.14	36.98
65 to 75 years	42,686	42,686	156,490	5,985,114	6,009,531	5,241,402	4,518,463,984	8.14	140.21	3.67	38.25
75 to 85 years	21,404	21,404	78,931	2,850,095	2,863,893	2,613,280	2,515,979,153	8.19	133.16	3.69	36.11
85+ years	6,933	6,933	29,706	957,567	957,790	997,942	874,684,879	6.95	138.12	4.28	32.23
<b>Escitalopram</b>											
0 to 41 years	506,022	506,022	1,508,083	48,861,885	49,457,072	50,814,719	39,309,055,894	9.96	96.56	2.98	32.40
41 to 55 years	337,313	337,313	1,237,390	42,400,834	42,852,074	20,845,958	16,401,951,750	16.18	125.70	3.67	34.27
55 to 65 years	157,507	157,507	628,284	22,818,060	22,930,263	11,188,864	9,029,690,980	14.08	144.87	3.99	36.32
65 to 75 years	61,428	61,428	225,049	8,288,512	8,327,796	5,221,716	4,489,012,966	11.76	134.93	3.66	36.83
75 to 85 years	40,560	40,560	159,751	5,543,777	5,575,550	2,599,061	2,492,816,059	15.61	136.68	3.94	34.70
85+ years	19,034	19,034	86,147	2,740,660	2,746,346	987,862	860,812,841	19.27	143.99	4.53	31.81

**Table 2. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Age Group**

	New Users	New Episodes	Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K Eligible Members	Average Days Supplied/ User	Average Dispensings/ User	Average Days Supplied/ Dispensing
<b>Fluoxetine</b>											
0 to 41 years	722,721	722,721	2,182,327	85,775,767	85,926,056	50,812,949	39,023,962,185	14.22	118.68	3.02	39.30
41 to 55 years	432,898	432,898	1,601,914	71,631,904	71,808,904	20,786,095	16,129,888,579	20.83	165.47	3.70	44.72
55 to 65 years	196,719	196,719	791,378	38,643,135	38,656,903	11,116,292	8,849,409,606	17.70	196.44	4.02	48.83
65 to 75 years	93,487	93,487	365,212	19,968,781	19,974,915	5,171,102	4,374,983,983	18.08	213.60	3.91	54.68
75 to 85 years	61,673	61,673	231,290	12,672,686	12,627,102	2,574,796	2,424,025,169	23.95	205.48	3.75	54.79
85+ years	22,148	22,148	81,416	4,114,966	4,059,088	977,303	839,854,977	22.66	185.79	3.68	50.54
<b>Paroxetine</b>											
0 to 41 years	351,206	351,206	1,008,988	36,119,780	36,303,222	50,885,203	39,344,796,969	6.90	102.84	2.87	35.80
41 to 55 years	233,251	233,251	848,943	33,105,892	33,260,138	20,894,273	16,402,339,683	11.16	141.93	3.64	39.00
55 to 65 years	114,818	114,818	453,217	18,725,960	18,760,284	11,191,025	8,999,495,366	10.26	163.09	3.95	41.32
65 to 75 years	61,434	61,434	234,364	10,662,283	10,674,572	5,196,550	4,435,592,318	11.82	173.56	3.81	45.49
75 to 85 years	40,632	40,632	156,030	6,973,885	6,963,700	2,582,263	2,456,424,242	15.74	171.64	3.84	44.70
85+ years	15,162	15,162	60,926	2,439,192	2,419,978	981,116	850,221,828	15.45	160.88	4.02	40.04
<b>Sertraline</b>											
0 to 41 years	791,258	791,258	2,482,029	84,515,688	85,102,174	50,727,879	39,039,440,332	15.60	106.81	3.14	34.05
41 to 55 years	397,535	397,535	1,463,075	53,114,184	53,431,643	20,764,718	16,283,330,939	19.14	133.61	3.68	36.30
55 to 65 years	192,931	192,931	758,445	29,216,867	29,273,847	11,124,186	8,947,336,488	17.34	151.44	3.93	38.52
65 to 75 years	92,706	92,706	356,426	14,587,917	14,617,660	5,178,718	4,432,139,986	17.90	157.36	3.84	40.93
75 to 85 years	64,823	64,823	258,986	10,092,935	10,115,122	2,576,214	2,456,189,172	25.16	155.70	4.00	38.97
85+ years	27,733	27,733	119,606	4,281,360	4,271,647	976,716	846,767,703	28.39	154.38	4.31	35.80
<b>Venlafaxine</b>											
0 to 41 years	270,954	270,954	1,003,623	33,716,406	33,937,691	50,872,184	39,465,710,585	5.33	124.44	3.70	33.59
41 to 55 years	244,598	244,598	1,100,215	39,894,147	40,147,111	20,875,595	16,455,586,117	11.72	163.10	4.50	36.26
55 to 65 years	110,673	110,673	503,316	19,492,964	19,550,118	11,190,282	9,044,215,885	9.89	176.13	4.55	38.73
65 to 75 years	37,956	37,956	154,709	6,234,421	6,255,687	5,225,596	4,499,072,817	7.26	164.25	4.08	40.30
75 to 85 years	17,563	17,563	75,972	2,872,381	2,882,505	2,608,927	2,510,651,571	6.73	163.55	4.33	37.81
85+ years	5,618	5,618	27,075	905,401	903,729	996,418	873,286,230	5.64	161.16	4.82	33.44

**Table 2. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Age Group**

	New Users	New Episodes	Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K Eligible Members	Average Days Supplied/ User	Average Dispensings/ User	Average Days Supplied/ Dispensing
<b>Vilazodone</b>											
0 to 41 years	3,478	3,478	5,621	176,790	174,223	50,984,645	39,758,917,676	0.07	50.83	1.62	31.45
41 to 55 years	3,796	3,796	6,240	202,374	200,140	21,081,447	16,803,810,941	0.18	53.31	1.64	32.43
55 to 65 years	1,857	1,857	3,204	106,490	106,172	11,342,431	9,249,745,308	0.16	57.35	1.73	33.24
65 to 75 years	451	451	771	26,969	26,802	5,273,272	4,561,726,134	0.09	59.80	1.71	34.98
75 to 85 years	115	115	189	6,553	6,573	2,625,567	2,536,791,220	0.04	56.98	1.64	34.67
85+ years	23	23	43	1,380	1,358	1,002,922	881,490,301	0.02	60.00	1.87	32.09

**Table 3. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Sex**

	New Users	New Episodes	Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K Eligible Members	Average Days Supplied/ User	Average Dispensings/ User	Average Days Supplied/ Dispensing
<b>Citalopram</b>											
Female	1,189,692	1,189,692	3,925,236	152,309,092	152,902,025	42,372,148	37,144,796,516	28.08	128.02	3.30	38.80
Male	553,348	553,348	1,826,711	70,224,190	70,394,901	40,873,640	35,062,814,484	13.54	126.91	3.30	38.44
Unknown	177	177	513	16,308	16,364	13,393	8,855,028	13.22	92.14	2.90	31.79
<b>Desvenlafaxine</b>											
Female	123,308	123,308	497,350	16,578,273	16,770,728	42,646,967	38,185,246,909	2.89	134.45	4.03	33.33
Male	44,093	44,093	174,648	5,797,069	5,850,521	40,994,186	35,507,622,689	1.08	131.47	3.96	33.19
Unknown	28	28	120	3,853	3,910	13,446	8,960,334	2.08	137.61	4.29	32.11
<b>Duloxetine</b>											
Female	426,869	426,869	1,611,594	56,166,906	56,561,070	42,504,440	37,854,932,441	10.04	131.58	3.78	34.85
Male	166,220	166,220	605,253	20,987,357	21,102,324	40,944,920	35,387,451,915	4.06	126.26	3.64	34.68
Unknown	75	75	303	11,168	11,070	13,412	8,920,274	5.59	148.91	4.04	36.86
<b>Escitalopram</b>											
Female	766,946	766,946	2,615,129	89,124,946	89,983,363	42,360,354	37,408,720,346	18.11	116.21	3.41	34.08
Male	354,783	354,783	1,229,113	41,514,028	41,890,905	40,862,638	35,165,779,690	8.68	117.01	3.46	33.78
Unknown	135	135	462	14,754	14,833	13,360	8,840,454	10.10	109.29	3.42	31.94
<b>Fluoxetine</b>											
Female	1,084,838	1,084,838	3,692,960	162,797,889	163,085,611	42,303,952	36,690,486,466	25.64	150.07	3.40	44.08
Male	444,682	444,682	1,560,249	69,996,066	69,954,183	40,879,187	34,942,800,679	10.88	157.41	3.51	44.86
Unknown	126	126	328	13,284	13,174	13,384	8,837,354	9.41	105.43	2.60	40.50
<b>Paroxetine</b>											
Female	535,318	535,318	1,808,670	71,008,683	71,262,174	42,446,233	37,360,473,812	12.61	132.65	3.38	39.26
Male	281,097	281,097	953,555	37,008,173	37,109,635	40,882,094	35,119,507,880	6.88	131.66	3.39	38.81
Unknown	88	88	243	10,136	10,085	13,402	8,888,714	6.57	115.18	2.76	41.71
<b>Sertraline</b>											
Female	1,078,754	1,078,754	3,710,664	134,324,306	135,049,323	42,195,479	36,985,476,396	25.57	124.52	3.44	36.20
Male	488,038	488,038	1,727,268	61,462,515	61,740,620	40,803,965	35,010,934,839	11.96	125.94	3.54	35.58
Unknown	194	194	635	22,130	22,150	13,330	8,793,385	14.55	114.07	3.27	34.85
<b>Venlafaxine</b>											
Female	507,565	507,565	2,120,098	76,604,813	77,046,871	42,396,632	37,544,934,215	11.97	150.93	4.18	36.13
Male	179,735	179,735	744,650	26,505,721	26,624,795	40,905,934	35,294,685,837	4.39	147.47	4.14	35.59

**Table 3. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Sex**

	<b>New Users</b>	<b>New Episodes</b>	<b>Dispensings</b>	<b>Total Days at Risk</b>	<b>Days at Risk</b>	<b>Eligible Members</b>	<b>Eligible Member-Days</b>	<b>New Users/ 1K Eligible Members</b>	<b>Average Days Supplied/ User</b>	<b>Average Dispensings/ User</b>	<b>Average Days Supplied/ Dispensing</b>
Unknown	62	62	162	5,186	5,175	13,388	8,903,153	4.63	83.65	2.61	32.01
<b>Vilazodone</b>											
Female	6,531	6,531	10,743	348,362	344,478	42,667,475	38,252,572,029	0.15	53.34	1.64	32.43
Male	3,188	3,188	5,319	172,039	170,635	41,001,129	35,530,938,257	0.08	53.96	1.67	32.34
Unknown	1	1	6	155	155	13,448	8,971,294	0.07	155.00	6.00	25.83

**Table 4. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Year**

	New Users	New Episodes	Dispensings	Total Days at Risk		Eligible Members	Eligible Member-Days	New Users/ 1K		Average Dispensings/ User	Average Days Supplied/ Dispensing
				Risk	Days at Risk			Eligible Members	Average Days Supplied/ User		
<b>Citalopram</b>											
2000	21,659	21,659	99,329	3,392,009	3,435,831	7,570,896	1,282,525,148	2.86	156.61	4.59	34.15
2001	49,058	49,058	215,081	7,342,088	7,440,457	8,146,953	2,527,533,270	6.02	149.66	4.38	34.14
2002	49,269	49,269	208,150	7,462,491	7,545,245	8,177,481	2,532,942,977	6.02	151.46	4.22	35.85
2003	27,078	27,078	108,407	4,591,712	4,618,393	8,099,972	2,513,391,472	3.34	169.57	4.00	42.36
2004	22,558	22,558	90,125	4,117,071	4,128,586	8,555,403	2,563,466,544	2.64	182.51	4.00	45.68
2005	57,991	57,991	220,121	10,609,391	10,590,651	8,633,384	2,624,600,031	6.72	182.95	3.80	48.20
2006	97,631	97,631	380,599	16,805,582	16,850,607	19,213,434	4,313,278,256	5.08	172.13	3.90	44.16
2007	131,043	131,043	499,187	20,575,245	20,679,929	22,869,186	6,103,621,245	5.73	157.01	3.81	41.22
2008	237,072	237,072	841,250	32,645,226	32,784,576	43,865,682	10,112,919,351	5.40	137.70	3.55	38.81
2009	333,753	333,753	1,132,447	42,677,912	42,845,069	45,644,769	12,992,942,449	7.31	127.87	3.39	37.69
2010	343,949	343,949	1,099,312	41,233,076	41,364,255	43,561,443	12,452,497,542	7.90	119.88	3.20	37.51
2011	372,156	372,156	858,452	31,097,787	31,029,691	42,267,267	12,196,747,743	8.80	83.56	2.31	36.23
<b>Desvenlafaxine</b>											
2000	0	0	0	0	0	7,593,946	1,289,029,800	0.00	---	---	---
2001	0	0	0	0	0	8,185,298	2,548,723,105	0.00	---	---	---
2002	0	0	0	0	0	8,259,440	2,568,932,056	0.00	---	---	---
2003	0	0	0	0	0	8,216,634	2,557,049,393	0.00	---	---	---
2004	0	0	0	0	0	8,687,972	2,610,594,289	0.00	---	---	---
2005	0	0	0	0	0	8,774,825	2,678,631,630	0.00	---	---	---
2006	0	0	0	0	0	19,427,370	4,388,684,471	0.00	---	---	---
2007	0	0	0	0	0	23,179,466	6,217,584,032	0.00	---	---	---
2008	22,365	22,365	95,900	3,273,672	3,305,746	44,420,313	10,300,877,733	0.50	146.37	4.29	34.14
2009	61,206	61,206	275,108	9,258,468	9,366,454	46,306,526	13,247,399,632	1.32	151.27	4.49	33.65
2010	46,589	46,589	195,855	6,449,938	6,527,003	44,347,061	12,747,375,595	1.05	138.44	4.20	32.93
2011	37,269	37,269	105,255	3,397,117	3,425,956	43,202,489	12,546,948,196	0.86	91.15	2.82	32.28

**Table 4. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Year**

	New Users	New Episodes	Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K Eligible Members	Average Days Supplied/ User	Average Dispensings/ User	Average Days Supplied/ Dispensing
<b>Duloxetine</b>											
2000	0	0	0	0	0	7,593,946	1,289,029,800	0.00	---	---	---
2001	0	0	0	0	0	8,185,298	2,548,723,105	0.00	---	---	---
2002	0	0	0	0	0	8,259,440	2,568,932,056	0.00	---	---	---
2003	0	0	0	0	0	8,216,634	2,557,049,393	0.00	---	---	---
2004	9,501	9,501	41,518	1,271,085	1,285,730	8,687,707	2,610,007,556	1.09	133.78	4.37	30.62
2005	23,473	23,473	88,448	2,931,316	2,947,292	8,763,599	2,670,569,620	2.68	124.88	3.77	33.14
2006	40,719	40,719	195,395	7,371,162	7,403,824	19,366,386	4,369,823,920	2.10	181.03	4.80	37.72
2007	65,618	65,618	305,828	11,001,211	11,095,120	23,067,280	6,177,020,910	2.84	167.66	4.66	35.97
2008	107,887	107,887	441,735	15,376,528	15,506,931	44,159,684	10,218,642,476	2.44	142.52	4.09	34.81
2009	128,161	128,161	494,820	17,163,920	17,287,734	46,024,142	13,145,198,150	2.78	133.92	3.86	34.69
2010	104,643	104,643	374,749	12,833,517	12,918,543	44,067,853	12,649,803,756	2.37	122.64	3.58	34.25
2011	113,162	113,162	274,657	9,216,692	9,229,290	42,921,892	12,446,503,888	2.64	81.45	2.43	33.56
<b>Escitalopram</b>											
2000	0	0	0	0	0	7,593,946	1,289,029,800	0.00	---	---	---
2001	0	0	0	0	0	8,185,298	2,548,723,105	0.00	---	---	---
2002	11,885	11,885	57,478	1,734,514	1,760,692	8,259,104	2,568,314,777	1.44	145.94	4.84	30.18
2003	53,899	53,899	246,786	7,774,644	7,891,949	8,199,916	2,543,318,905	6.57	144.24	4.58	31.50
2004	59,146	59,146	244,301	7,755,442	7,862,066	8,614,884	2,576,964,369	6.87	131.12	4.13	31.75
2005	35,674	35,674	117,118	3,784,426	3,816,709	8,652,382	2,632,778,890	4.12	106.08	3.28	32.31
2006	77,131	77,131	306,685	11,304,899	11,368,887	19,176,128	4,320,394,092	4.02	146.57	3.98	36.86
2007	121,142	121,142	491,757	17,071,790	17,277,179	22,860,396	6,107,696,028	5.30	140.92	4.06	34.72
2008	201,581	201,581	710,516	24,218,273	24,481,828	43,817,718	10,112,603,369	4.60	120.14	3.52	34.09
2009	229,676	229,676	758,795	26,010,370	26,242,954	45,685,547	13,018,993,543	5.03	113.25	3.30	34.28
2010	184,196	184,196	570,321	19,464,741	19,618,882	43,733,267	12,529,470,343	4.21	105.67	3.10	34.13
2011	147,534	147,534	340,947	11,534,629	11,567,955	42,602,627	12,335,053,269	3.46	78.18	2.31	33.83

**Table 4. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Year**

	New Users	New Episodes	New Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K Eligible Members	Average Days Supplied/ User	Average Dispensings/ User	Average Days Supplied/ Dispensing
<b>Fluoxetine</b>											
2000	31,647	31,647	129,210	5,525,014	5,553,485	7,494,086	1,266,713,041	4.22	174.58	4.08	42.76
2001	79,168	79,168	322,385	15,004,385	15,064,407	8,079,409	2,497,936,648	9.80	189.53	4.07	46.54
2002	102,466	102,466	405,221	21,596,116	21,597,207	8,091,408	2,493,956,031	12.66	210.76	3.95	53.29
2003	104,192	104,192	399,667	22,113,965	22,093,874	7,972,774	2,457,099,978	13.07	212.24	3.84	55.33
2004	98,138	98,138	366,662	19,988,393	19,960,256	8,356,796	2,484,635,303	11.74	203.68	3.74	54.51
2005	83,828	83,828	294,942	15,641,816	15,610,152	8,389,042	2,535,860,977	9.99	186.59	3.52	53.03
2006	106,740	106,740	393,920	18,822,473	18,817,682	18,913,066	4,218,786,633	5.64	176.34	3.69	47.78
2007	126,337	126,337	465,216	20,508,530	20,555,657	22,592,122	6,011,728,757	5.59	162.33	3.68	44.08
2008	178,634	178,634	620,529	24,567,972	24,637,385	43,609,179	10,034,737,989	4.10	137.53	3.47	39.59
2009	219,078	219,078	743,755	28,121,678	28,218,571	45,480,186	12,949,313,811	4.82	128.36	3.39	37.81
2010	201,544	201,544	651,826	24,285,122	24,367,834	43,514,365	12,451,001,263	4.63	120.50	3.23	37.26
2011	197,874	197,874	460,204	16,631,775	16,576,458	42,340,920	12,240,354,068	4.67	84.05	2.33	36.14
<b>Paroxetine</b>											
2000	45,591	45,591	174,033	7,635,694	7,663,860	7,502,543	1,266,599,880	6.08	167.48	3.82	43.87
2001	84,034	84,034	311,244	13,658,534	13,703,712	8,077,861	2,495,185,758	10.40	162.54	3.70	43.88
2002	78,925	78,925	305,857	12,484,108	12,549,839	8,089,142	2,496,855,645	9.76	158.18	3.88	40.82
2003	55,453	55,453	207,605	8,761,283	8,792,263	7,996,414	2,472,884,567	6.93	157.99	3.74	42.20
2004	44,535	44,535	162,219	7,078,138	7,083,178	8,433,319	2,518,154,618	5.28	158.93	3.64	43.63
2005	31,838	31,838	101,761	4,522,212	4,512,464	8,507,749	2,585,070,138	3.74	142.04	3.20	44.44
2006	46,808	46,808	171,284	7,019,004	7,030,666	19,109,293	4,290,218,263	2.45	149.95	3.66	40.98
2007	55,138	55,138	204,427	7,625,077	7,665,714	22,828,687	6,101,212,228	2.42	138.29	3.71	37.30
2008	87,530	87,530	301,107	10,481,225	10,540,072	43,943,158	10,151,510,704	1.99	119.74	3.44	34.81
2009	107,583	107,583	347,796	12,120,593	12,176,492	45,850,481	13,091,146,775	2.35	112.66	3.23	34.85
2010	93,482	93,482	286,178	10,071,718	10,113,480	43,937,026	12,606,853,376	2.13	107.74	3.06	35.19
2011	85,586	85,586	188,957	6,569,406	6,550,154	42,814,638	12,413,178,454	2.00	76.76	2.21	34.77

**Table 4. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Year**

	New Users	New Episodes	Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K Eligible Members	Average Days Supplied/ User	Average Dispensings/ User	Average Days Supplied/ Dispensing
<b>Sertraline</b>											
2000	28,136	28,136	114,252	4,065,378	4,105,090	7,528,336	1,273,719,433	3.74	144.49	4.06	35.58
2001	57,196	57,196	238,172	8,417,130	8,516,926	8,110,176	2,512,817,773	7.05	147.16	4.16	35.34
2002	55,362	55,362	230,610	8,252,791	8,340,556	8,140,868	2,519,231,528	6.80	149.07	4.17	35.79
2003	52,919	52,919	210,777	7,794,883	7,870,720	8,060,766	2,496,395,583	6.57	147.30	3.98	36.98
2004	48,974	48,974	190,188	6,970,808	7,024,443	8,490,052	2,537,765,230	5.77	142.34	3.88	36.65
2005	35,565	35,565	120,945	4,554,234	4,573,439	8,555,111	2,600,902,020	4.16	128.05	3.40	37.66
2006	74,065	74,065	312,935	11,872,956	11,928,490	19,089,724	4,292,129,093	3.88	160.30	4.23	37.94
2007	120,436	120,436	481,316	17,926,728	18,050,089	22,768,120	6,079,247,645	5.29	148.85	4.00	37.25
2008	219,051	219,051	815,626	29,422,442	29,588,539	43,690,766	10,075,597,493	5.01	134.32	3.72	36.07
2009	302,823	302,823	1,092,454	39,039,842	39,221,083	45,517,235	12,958,737,340	6.65	128.92	3.61	35.74
2010	285,441	285,441	957,817	34,021,614	34,173,021	43,494,866	12,441,720,987	6.56	119.19	3.36	35.52
2011	287,018	287,018	673,475	23,470,145	23,419,697	42,280,311	12,216,940,495	6.79	81.77	2.35	34.85
<b>Venlafaxine</b>											
2000	12,288	12,288	62,990	2,262,922	2,282,585	7,573,949	1,283,982,112	1.62	184.16	5.13	35.93
2001	29,027	29,027	145,632	5,287,505	5,335,351	8,157,882	2,534,373,641	3.56	182.16	5.02	36.31
2002	38,909	38,909	188,830	6,790,977	6,848,865	8,206,007	2,544,633,476	4.74	174.53	4.85	35.96
2003	42,134	42,134	197,359	7,465,054	7,519,089	8,130,465	2,521,301,994	5.18	177.17	4.68	37.82
2004	36,894	36,894	166,840	6,309,540	6,350,679	8,564,255	2,563,568,908	4.31	171.02	4.52	37.82
2005	25,384	25,384	102,642	4,181,577	4,194,994	8,628,749	2,626,688,880	2.94	164.73	4.04	40.74
2006	44,716	44,716	219,929	8,503,794	8,525,087	19,211,938	4,326,343,690	2.33	190.17	4.92	38.67
2007	65,644	65,644	325,844	11,740,225	11,833,322	22,926,869	6,131,893,425	2.86	178.85	4.96	36.03
2008	94,456	94,456	423,361	14,833,295	14,929,245	43,980,690	10,170,541,315	2.15	157.04	4.48	35.04
2009	100,258	100,258	414,035	14,567,058	14,633,466	45,877,977	13,104,049,981	2.19	145.30	4.13	35.18
2010	95,573	95,573	362,783	12,584,896	12,641,825	43,970,753	12,619,947,350	2.17	131.68	3.80	34.69
2011	102,079	102,079	254,665	8,588,877	8,582,333	42,837,734	12,421,198,433	2.38	84.14	2.49	33.73

**Table 4. Summary of Incident Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressant Use in the MSDD between January 1, 2000 and December 31, 2011, by Drug Product and Year**

	New Users	New Episodes	Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K Eligible Members	Average Days Supplied/ User	Average Dispensings/ User	Average Days Supplied/ Dispensing
<b>Vilazodone</b>											
2000	0	0	0	0	0	7,593,946	1,289,029,800	0.00	---	---	---
2001	0	0	0	0	0	8,185,298	2,548,723,105	0.00	---	---	---
2002	0	0	0	0	0	8,259,440	2,568,932,056	0.00	---	---	---
2003	0	0	0	0	0	8,216,634	2,557,049,393	0.00	---	---	---
2004	0	0	0	0	0	8,687,972	2,610,594,289	0.00	---	---	---
2005	0	0	0	0	0	8,774,825	2,678,631,630	0.00	---	---	---
2006	0	0	0	0	0	19,427,370	4,388,684,471	0.00	---	---	---
2007	0	0	0	0	0	23,179,466	6,217,584,032	0.00	---	---	---
2008	0	0	0	0	0	44,422,776	10,302,856,430	0.00	---	---	---
2009	0	0	0	0	0	46,337,529	13,265,226,293	0.00	---	---	---
2010	0	0	0	0	0	44,428,973	12,779,667,433	0.00	---	---	---
2011	9,720	9,720	16,068	520,556	515,268	43,308,968	12,585,502,648	0.22	53.56	1.65	32.40

**Appendix A. Available Data in the Mini-Sentinel Distributed Database (MSDD) for Each Data Partner as of Request Send Date (June 10, 2013)**

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<b>Data Partner ID</b>	<b>Start Date</b>	<b>End Date</b>
DP001	1/31/2000	12/31/2011
DP002	1/2/2000	12/31/2011
DP003	1/1/2000	12/31/2011
DP004	1/1/2000	12/31/2011
DP005	1/2/2000	12/31/2011
DP006	1/1/2000	12/31/2011
DP007	1/2/2000	12/31/2011
DP008	1/1/2000	12/31/2011
DP009	1/31/2000	12/31/2011
DP010	1/2/2000	12/31/2011
DP011	6/2/2007	12/31/2011
DP012	1/2/2008	12/31/2011
DP013	1/1/2000	12/31/2011
DP014	1/2/2008	12/31/2011
DP015	1/2/2005	12/31/2011
DP016	1/1/2000	12/31/2011
DP017	1/1/2000	12/31/2011
DP018	1/2/2006	12/31/2011

**Appendix B. Specifications for Request MSY4\_MPR38\_V1**

Modular Program #3 was used to investigate the use of several Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants. No event was queried. MP3 was used to require both drug and medical coverage among users. The query period is from January 1, 2000 to December 31, 2011. The enrollment gap was set to 45 days and episode extension, minimum days supplied and minimum episode duration were all set to 0 days. Age groups were split as follows: 0<41, 41<55, 55<65, 65<75, 75<85, 85+ years. In total, nine different drug products were examined in this request. See below for a description of each of these scenarios.

Scenario	Drug/Exposure					Event/Outcome
	Incident exposure	Incident w/ respect to:	Washout (days)	Incidence Type	Episode Gap	Event/ Outcome
1	Citalopram	Citalopram	183	Sing	10	None
2	Desvenlafaxine	Desvenlafaxine	183	Sing	10	None
3	Duloxetine	Duloxetine	183	Sing	10	None
4	Escitalopram	Escitalopram	183	Sing	10	None
5	Fluoxetine	Fluoxetine	183	Sing	10	None
6	Paroxetine	Paroxetine	183	Sing	10	None
7	Sertraline	Sertraline	183	Sing	10	None
8	Venlafaxine	Venlafaxine	183	Sing	10	None
9	Vilazodone	Vilazodone	183	Sing	10	None

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

International Classification of Diseases (ICD-9-CM) diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

Healthcare Common Procedure Coding System (HCPCS) codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

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