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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

<u>Request Description</u>	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 second run are presented in this report. The first report presents incidence of each drug with respect to the SSRI of interest. A user was considered a new user if he/she was not exposed to the drug products 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.
<u>Request ID</u>	msy4_mpr38_v1
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<u>Appendix B</u>	Specifications for Request MSY4_MPR38_V1
<u>Notes:</u>	<p>Please refer to the Sentinel Distributed Query Tool Summary Table documentation and Investigator manual on the Sentinel website (https://www.sentinelinitiative.org/sentinel/routine-querying-tools/summary-table-queries) for more details.</p> <p>Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.</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 Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2011, by Drug Product

	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/	Average Dispensings/ User	Average Days Supplied/
Citalopram	1,302,505	1,302,505	4,018,869	153,589,634	152,678,368	80,393,889	67,765,434,584	16.20	117.92	3.09	38.22
Desvenlafaxine	75,290	75,290	266,644	8,754,304	8,816,455	80,393,905	68,078,858,356	0.94	116.27	3.54	32.83
Duloxetine	326,646	326,646	1,034,107	35,653,135	35,655,047	80,393,905	68,019,949,741	4.06	109.15	3.17	34.48
Escitalopram	847,651	847,651	2,700,414	91,766,227	91,906,481	80,393,899	67,877,010,083	10.54	108.26	3.19	33.98
Fluoxetine	638,431	638,431	2,052,635	81,044,295	80,373,746	80,393,902	67,752,133,910	7.94	126.94	3.22	39.48
Paroxetine	1,239,691	1,239,691	4,082,196	145,398,124	145,047,560	80,393,894	67,739,256,390	15.42	117.29	3.29	35.62
Sertraline	1,246,156	1,246,156	4,063,771	186,713,514	184,953,191	80,393,888	67,488,965,824	15.50	149.83	3.26	45.95
Venlafaxine	383,642	383,642	1,395,523	50,198,968	50,012,689	80,393,896	67,948,931,054	4.77	130.85	3.64	35.97
Vilazodone	3,194	3,194	5,003	160,415	157,061	80,393,908	68,086,503,959	0.04	50.22	1.57	32.06

Table 2. 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

	New Users	New Episodes	Dispensings	Total Days at Risk	Days at Risk	Eligible Members	Eligible Member-Days	New Users/ 1K		Average Dispensings/ User	Average Days Supplied/ Dispensing
								Eligible Members	Average Days Supplied/ User		
Citalopram											
0 to 41 years	563,715	563,715	1,524,895	53,742,582	53,439,198	49,861,130	37,812,954,215	11.31	95.34	2.71	35.24
41 to 55 years	363,224	363,224	1,168,262	44,472,751	44,284,165	19,650,826	14,847,340,754	18.48	122.44	3.22	38.07
55 to 65 years	185,157	185,157	629,498	25,776,312	25,590,796	10,378,466	8,046,193,507	17.84	139.21	3.40	40.95
65 to 75 years	92,979	92,979	320,873	14,239,808	14,143,569	4,874,232	4,050,890,804	19.08	153.15	3.45	44.38
75 to 85 years	66,901	66,901	247,638	10,492,408	10,414,104	2,439,652	2,246,023,636	27.42	156.83	3.70	42.37
85+ years	30,529	30,529	127,703	4,865,773	4,806,536	914,127	762,031,668	33.40	159.38	4.18	38.10
Desvenlafaxine											
0 to 41 years	33,417	33,417	107,422	3,383,586	3,414,725	49,861,134	37,937,735,470	0.67	101.25	3.21	31.50
41 to 55 years	27,930	27,930	106,339	3,505,933	3,536,564	19,684,864	14,938,497,885	1.42	125.53	3.81	32.97
55 to 65 years	10,884	10,884	43,063	1,495,757	1,497,867	10,410,072	8,098,056,742	1.05	137.43	3.96	34.73
65 to 75 years	2,108	2,108	6,846	262,824	261,556	4,887,446	4,073,797,953	0.43	124.68	3.25	38.39
75 to 85 years	756	756	2,273	82,216	81,745	2,448,814	2,261,900,828	0.31	108.75	3.01	36.17
85+ years	195	195	701	23,988	23,998	919,981	768,869,478	0.21	123.02	3.59	34.22
Duloxetine											
0 to 41 years	102,941	102,941	286,822	9,217,453	9,219,478	49,861,134	37,922,327,242	2.06	89.54	2.79	32.14
41 to 55 years	116,167	116,167	382,465	13,074,641	13,098,059	19,678,340	14,918,446,056	5.90	112.55	3.29	34.19
55 to 65 years	64,391	64,391	225,751	8,255,008	8,237,201	10,402,511	8,084,921,096	6.19	128.20	3.51	36.57
65 to 75 years	25,364	25,364	80,458	3,059,879	3,056,652	4,884,317	4,068,367,105	5.19	120.64	3.17	38.03
75 to 85 years	13,373	13,373	42,219	1,519,376	1,519,945	2,446,687	2,258,276,001	5.47	113.62	3.16	35.99
85+ years	4,410	4,410	16,392	526,778	523,712	918,843	767,612,241	4.80	119.45	3.72	32.14
Escitalopram											
0 to 41 years	389,531	389,531	1,091,838	35,343,210	35,447,613	49,861,133	37,848,124,456	7.81	90.73	2.80	32.37
41 to 55 years	250,259	250,259	843,463	28,926,569	29,035,666	19,660,529	14,876,961,993	12.73	115.59	3.37	34.30
55 to 65 years	116,423	116,423	429,526	15,630,866	15,600,573	10,389,877	8,066,958,218	11.21	134.26	3.69	36.39
65 to 75 years	45,744	45,744	155,693	5,766,791	5,745,277	4,880,771	4,063,730,547	9.37	126.07	3.40	37.04
75 to 85 years	30,815	30,815	114,368	4,002,435	3,991,487	2,444,714	2,255,322,373	12.60	129.89	3.71	35.00
85+ years	14,879	14,879	65,526	2,096,356	2,085,865	917,394	765,912,496	16.22	140.89	4.40	31.99

Table 2. 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

	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
Fluoxetine											
0 to 41 years	591,731	591,731	1,691,837	68,485,479	67,761,956	49,861,129	37,716,966,670	11.87	115.74	2.86	40.48
41 to 55 years	347,942	347,942	1,215,210	56,585,858	56,179,427	19,626,766	14,764,908,440	17.73	162.63	3.49	46.56
55 to 65 years	157,206	157,206	604,864	30,818,842	30,570,691	10,354,530	8,000,672,483	15.18	196.04	3.85	50.95
65 to 75 years	76,901	76,901	289,545	16,391,020	16,243,130	4,861,095	4,024,945,187	15.82	213.14	3.77	56.61
75 to 85 years	52,998	52,998	192,854	10,846,281	10,694,924	2,431,090	2,226,750,360	21.80	204.65	3.64	56.24
85+ years	19,378	19,378	69,461	3,586,034	3,503,063	909,015	754,722,684	21.32	185.06	3.58	51.63
Paroxetine											
0 to 41 years	274,219	274,219	751,051	27,094,666	26,830,443	49,861,135	37,816,261,122	5.50	98.81	2.74	36.08
41 to 55 years	180,136	180,136	620,193	24,483,484	24,327,033	19,652,948	14,842,432,821	9.17	135.92	3.44	39.48
55 to 65 years	89,883	89,883	336,277	14,063,257	13,961,665	10,379,245	8,042,320,954	8.66	156.46	3.74	41.82
65 to 75 years	48,926	48,926	176,539	8,081,319	8,020,322	4,873,100	4,046,687,198	10.04	165.17	3.61	45.78
75 to 85 years	32,802	32,802	120,095	5,364,952	5,306,883	2,438,737	2,242,852,896	13.45	163.56	3.66	44.67
85+ years	12,465	12,465	48,480	1,956,617	1,927,400	914,306	761,578,919	13.63	156.97	3.89	40.36
Sertraline											
0 to 41 years	638,961	638,961	1,918,376	64,804,341	64,698,610	49,861,129	37,770,732,703	12.81	101.42	3.00	33.78
41 to 55 years	305,713	305,713	1,056,432	37,993,293	37,949,595	19,649,345	14,851,046,385	15.56	124.28	3.46	35.96
55 to 65 years	148,062	148,062	549,607	20,930,273	20,832,906	10,381,494	8,051,787,703	14.26	141.36	3.71	38.08
65 to 75 years	72,053	72,053	263,940	10,660,303	10,609,313	4,876,270	4,054,752,698	14.78	147.95	3.66	40.39
75 to 85 years	51,867	51,867	197,987	7,605,128	7,577,615	2,441,023	2,248,011,943	21.25	146.63	3.82	38.41
85+ years	23,035	23,035	95,854	3,404,786	3,379,521	914,966	762,924,958	25.18	147.81	4.16	35.52
Venlafaxine											
0 to 41 years	146,246	146,246	476,080	15,929,606	15,848,869	49,861,132	37,892,372,397	2.93	108.92	3.26	33.46
41 to 55 years	140,578	140,578	550,251	19,887,180	19,851,016	19,671,660	14,895,094,642	7.15	141.47	3.91	36.14
55 to 65 years	63,294	63,294	249,045	9,712,049	9,665,567	10,393,182	8,070,444,592	6.09	153.44	3.93	39.00
65 to 75 years	20,907	20,907	73,014	2,949,120	2,935,482	4,881,797	4,065,183,372	4.28	141.06	3.49	40.39
75 to 85 years	9,564	9,564	34,661	1,300,235	1,294,187	2,446,399	2,258,086,732	3.91	135.95	3.62	37.51
85+ years	3,053	3,053	12,472	420,778	417,568	918,934	767,749,319	3.32	137.82	4.09	33.74

Table 2. 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

	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		
Vilazodone											
0 to 41 years	1,283	1,283	1,954	60,819	59,256	49,861,136	37,940,925,867	0.03	47.40	1.52	31.13
41 to 55 years	1,199	1,199	1,880	60,338	59,346	19,686,213	14,941,357,176	0.06	50.32	1.57	32.09
55 to 65 years	550	550	919	30,415	29,731	10,411,167	8,099,285,148	0.05	55.30	1.67	33.10
65 to 75 years	122	122	192	6,675	6,626	4,887,682	4,074,042,241	0.02	54.71	1.57	34.77
75 to 85 years	34	34	48	1,868	1,797	2,448,894	2,261,993,639	0.01	54.94	1.41	38.92
85+ years	6	6	10	300	305	920,016	768,899,888	0.01	50.00	1.67	30.00

Table 3. 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

	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	
Citalopram												
Female	869,176	869,176	2,668,996	102,233,877	101,656,239	40,314,419	33,977,167,201	21.56	117.62	3.07	38.30	
Male	433,192	433,192	1,349,518	51,344,073	51,010,608	40,066,518	33,779,874,045	10.81	118.52	3.12	38.05	
Unknown	137	137	355	11,684	11,521	12,952	8,393,338	10.58	85.28	2.59	32.91	
Desvenlafaxine												
Female	53,696	53,696	191,078	6,286,602	6,335,509	40,314,432	34,188,140,282	1.33	117.08	3.56	32.90	
Male	21,580	21,580	75,509	2,465,752	2,478,955	40,066,521	33,882,305,086	0.54	114.26	3.50	32.66	
Unknown	14	14	57	1,950	1,991	12,952	8,412,988	1.08	139.29	4.07	34.21	
Duloxetine												
Female	224,492	224,492	713,787	24,653,050	24,660,399	40,314,431	34,148,832,926	5.57	109.82	3.18	34.54	
Male	102,114	102,114	320,164	10,994,513	10,989,103	40,066,522	33,862,706,656	2.55	107.67	3.14	34.34	
Unknown	40	40	156	5,572	5,545	12,952	8,410,159	3.09	139.30	3.90	35.72	
Escitalopram												
Female	566,333	566,333	1,781,780	60,793,175	60,874,908	40,314,427	34,053,448,244	14.05	107.35	3.15	34.12	
Male	281,207	281,207	918,241	30,960,358	31,018,963	40,066,520	33,815,160,075	7.02	110.10	3.27	33.72	
Unknown	111	111	393	12,694	12,610	12,952	8,401,764	8.57	114.36	3.54	32.30	
Fluoxetine												
Female	872,610	872,610	2,804,285	128,413,390	127,293,757	40,314,420	33,779,219,995	21.65	147.16	3.21	45.79	
Male	373,442	373,442	1,259,216	58,288,730	57,648,300	40,066,516	33,701,354,836	9.32	156.09	3.37	46.29	
Unknown	104	104	270	11,394	11,134	12,952	8,390,993	8.03	109.56	2.60	42.20	
Paroxetine												
Female	409,798	409,798	1,311,721	52,152,189	51,701,811	40,314,433	33,971,410,956	10.17	127.26	3.20	39.76	
Male	228,565	228,565	740,746	28,884,707	28,664,673	40,066,517	33,772,324,173	5.70	126.37	3.24	38.99	
Unknown	68	68	168	7,399	7,262	12,952	8,398,781	5.25	108.81	2.47	44.04	
Sertraline												
Female	840,186	840,186	2,726,729	97,703,804	97,457,483	40,314,423	33,956,599,688	20.84	116.29	3.25	35.83	
Male	399,353	399,353	1,354,994	47,678,155	47,573,877	40,066,519	33,774,264,795	9.97	119.39	3.39	35.19	
Unknown	152	152	473	16,165	16,200	12,952	8,391,907	11.74	106.35	3.11	34.18	
Venlafaxine												
Female	280,581	280,581	1,018,210	36,834,218	36,707,385	40,314,429	34,092,460,751	6.96	131.28	3.63	36.18	
Male	103,027	103,027	377,232	13,362,252	13,302,868	40,066,515	33,848,062,133	2.57	129.70	3.66	35.42	
Unknown	34	34	81	2,498	2,436	12,952	8,408,170	2.63	73.47	2.38	30.84	

Table 3. 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

	New Users	New Episodes	Dispensings	Total Days at Risk		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		
Vilazodone											
Female	1,991	1,991	3,049	97,006	94,617	40,314,434	34,193,446,123	0.05	48.72	1.53	31.82
Male	1,203	1,203	1,954	63,409	62,444	40,066,522	33,884,643,253	0.03	52.71	1.62	32.45
Unknown	0	0	0	0	0	12,952	8,414,583	0.00	---	---	---

Table 4. 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

	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
Citalopram											
2000	14,180	14,180	60,058	1,989,864	2,002,107	7,295,130	1,222,483,968	1.94	140.33	4.24	33.13
2001	33,219	33,219	136,233	4,521,535	4,551,560	7,883,217	2,399,561,479	4.21	136.11	4.10	33.19
2002	33,497	33,497	133,560	4,603,610	4,619,931	7,878,839	2,386,966,485	4.25	137.43	3.99	34.47
2003	17,264	17,264	64,219	2,511,091	2,502,338	7,763,192	2,350,651,408	2.22	145.45	3.72	39.10
2004	13,936	13,936	52,126	2,209,017	2,195,479	8,147,354	2,379,548,130	1.71	158.51	3.74	42.38
2005	33,063	33,063	118,988	5,711,532	5,649,684	8,210,727	2,441,505,099	4.03	172.75	3.60	48.00
2006	65,152	65,152	231,811	10,282,541	10,198,484	18,271,903	4,049,029,531	3.57	157.82	3.56	44.36
2007	96,652	96,652	346,586	14,142,069	14,091,222	21,746,151	5,718,576,063	4.44	146.32	3.59	40.80
2008	177,452	177,452	589,937	22,851,238	22,737,285	41,706,705	9,467,301,558	4.25	128.77	3.32	38.74
2009	254,769	254,769	812,967	30,535,886	30,393,994	43,555,610	12,181,585,728	5.85	119.86	3.19	37.56
2010	269,230	269,230	819,305	30,578,588	30,413,158	41,593,605	11,694,155,096	6.47	113.58	3.04	37.32
2011	294,091	294,091	653,079	23,652,663	23,323,126	40,410,445	11,474,070,039	7.28	80.43	2.22	36.22
Desvenlafaxine											
2000	0	0	0	0	0	7,295,130	1,222,483,968	0.00	---	---	---
2001	0	0	0	0	0	7,889,226	2,400,741,553	0.00	---	---	---
2002	0	0	0	0	0	7,900,719	2,391,908,653	0.00	---	---	---
2003	0	0	0	0	0	7,799,828	2,359,295,682	0.00	---	---	---
2004	0	0	0	0	0	8,191,046	2,390,513,438	0.00	---	---	---
2005	0	0	0	0	0	8,257,637	2,453,629,602	0.00	---	---	---
2006	0	0	0	0	0	18,324,956	4,062,471,075	0.00	---	---	---
2007	0	0	0	0	0	21,826,104	5,738,924,200	0.00	---	---	---
2008	8,718	8,718	31,997	1,072,344	1,077,486	41,830,114	9,498,682,656	0.21	123.00	3.67	33.51
2009	26,945	26,945	107,262	3,556,795	3,589,656	43,750,842	12,230,263,222	0.62	132.00	3.98	33.16
2010	21,759	21,759	80,823	2,627,079	2,648,674	41,869,440	11,764,091,621	0.52	120.74	3.71	32.50
2011	17,868	17,868	46,562	1,498,086	1,500,639	40,767,373	11,565,852,686	0.44	83.84	2.61	32.17

Table 4. 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

	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
Duloxetine											
2000	0	0	0	0	0	7,295,130	1,222,483,968	0.00	---	---	---
2001	0	0	0	0	0	7,889,226	2,400,741,553	0.00	---	---	---
2002	0	0	0	0	0	7,900,719	2,391,908,653	0.00	---	---	---
2003	0	0	0	0	0	7,799,828	2,359,295,682	0.00	---	---	---
2004	3,119	3,119	9,833	295,744	296,661	8,191,046	2,390,513,438	0.38	94.82	3.15	30.08
2005	9,187	9,187	26,456	861,441	858,971	8,256,033	2,453,311,751	1.11	93.77	2.88	32.56
2006	19,610	19,610	75,921	2,783,256	2,774,403	18,319,428	4,061,168,398	1.07	141.93	3.87	36.66
2007	33,236	33,236	129,044	4,534,830	4,548,733	21,812,130	5,735,650,736	1.52	136.44	3.88	35.14
2008	58,881	58,881	203,709	7,019,327	7,034,747	41,801,000	9,491,560,639	1.41	119.21	3.46	34.46
2009	73,532	73,532	244,826	8,461,386	8,470,443	43,702,261	12,218,422,419	1.68	115.07	3.33	34.56
2010	60,960	60,960	192,018	6,567,904	6,572,248	41,806,289	11,747,901,317	1.46	107.74	3.15	34.20
2011	68,121	68,121	152,300	5,129,247	5,098,841	40,695,677	11,546,991,187	1.67	75.30	2.24	33.68
Escitalopram											
2000	0	0	0	0	0	7,295,130	1,222,483,968	0.00	---	---	---
2001	0	0	0	0	0	7,889,226	2,400,741,553	0.00	---	---	---
2002	4,730	4,730	18,445	551,499	555,263	7,900,719	2,391,908,653	0.60	116.60	3.90	29.90
2003	28,939	28,939	115,158	3,624,286	3,650,890	7,797,838	2,358,852,716	3.71	125.24	3.98	31.47
2004	37,431	37,431	137,821	4,329,531	4,355,251	8,174,820	2,387,004,949	4.58	115.67	3.68	31.41
2005	23,943	23,943	70,871	2,254,339	2,249,751	8,222,599	2,445,661,265	2.91	94.15	2.96	31.81
2006	60,148	60,148	223,001	8,156,359	8,124,714	18,285,859	4,052,777,980	3.29	135.60	3.71	36.58
2007	94,665	94,665	360,762	12,434,593	12,498,193	21,766,166	5,724,424,370	4.35	131.35	3.81	34.47
2008	158,954	158,954	531,503	18,063,676	18,142,528	41,731,276	9,474,603,645	3.81	113.64	3.34	33.99
2009	179,522	179,522	561,842	19,195,607	19,233,551	43,598,941	12,194,102,196	4.12	106.93	3.13	34.17
2010	144,473	144,473	423,870	14,445,568	14,447,040	41,672,821	11,715,425,348	3.47	99.99	2.93	34.08
2011	114,846	114,846	257,141	8,710,769	8,649,300	40,542,864	11,509,023,440	2.83	75.85	2.24	33.88

Table 4. 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

	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
Fluoxetine											
2000	25,846	25,846	98,955	4,294,759	4,282,573	7,295,130	1,222,483,968	3.54	166.17	3.83	43.40
2001	64,489	64,489	246,243	11,752,785	11,699,115	7,877,815	2,398,595,228	8.19	182.24	3.82	47.73
2002	87,000	87,000	328,503	17,966,301	17,777,165	7,856,649	2,382,106,281	11.07	206.51	3.78	54.69
2003	90,768	90,768	331,547	18,899,554	18,683,395	7,713,141	2,338,647,820	11.77	208.22	3.65	57.00
2004	85,602	85,602	304,418	17,065,543	16,850,723	8,059,342	2,357,513,468	10.62	199.36	3.56	56.06
2005	72,255	72,255	244,646	13,475,395	13,283,891	8,086,453	2,408,779,131	8.94	186.50	3.39	55.08
2006	90,060	90,060	314,324	15,594,225	15,405,122	18,127,685	4,009,081,901	4.97	173.15	3.49	49.61
2007	103,915	103,915	357,128	16,386,899	16,236,996	21,597,020	5,676,263,868	4.81	157.70	3.44	45.89
2008	141,653	141,653	462,195	18,879,694	18,741,627	41,561,507	9,424,829,647	3.41	133.28	3.26	40.85
2009	172,394	172,394	549,235	21,307,036	21,185,218	43,436,039	12,144,565,563	3.97	123.59	3.19	38.79
2010	157,769	157,769	480,079	18,312,371	18,208,932	41,514,811	11,667,131,454	3.80	116.07	3.04	38.14
2011	154,405	154,405	346,498	12,778,952	12,598,434	40,379,031	11,458,967,495	3.82	82.76	2.24	36.88
Paroxetine											
2000	39,250	39,250	143,351	6,381,210	6,332,009	7,295,130	1,222,483,968	5.38	162.58	3.65	44.51
2001	71,005	71,005	252,050	11,244,484	11,144,306	7,870,774	2,397,137,030	9.02	158.36	3.55	44.61
2002	62,188	62,188	230,467	9,469,206	9,411,203	7,843,833	2,378,533,903	7.93	152.27	3.71	41.09
2003	42,446	42,446	150,262	6,339,165	6,282,591	7,714,634	2,338,095,903	5.50	149.35	3.54	42.19
2004	33,038	33,038	115,511	4,996,548	4,933,760	8,087,072	2,363,506,665	4.09	151.24	3.50	43.26
2005	23,520	23,520	70,710	3,185,504	3,130,998	8,142,981	2,423,103,090	2.89	135.44	3.01	45.05
2006	35,974	35,974	124,142	5,121,504	5,065,246	18,215,095	4,032,333,097	1.97	142.37	3.45	41.26
2007	42,395	42,395	147,814	5,538,736	5,510,653	21,707,460	5,705,917,409	1.95	130.65	3.49	37.47
2008	67,200	67,200	217,053	7,586,726	7,555,009	41,697,259	9,461,906,863	1.61	112.90	3.23	34.95
2009	83,129	83,129	252,722	8,850,620	8,805,324	43,600,396	12,189,390,512	1.91	106.47	3.04	35.02
2010	72,318	72,318	208,449	7,391,759	7,344,896	41,709,460	11,719,961,563	1.73	102.21	2.88	35.46
2011	65,968	65,968	140,104	4,938,833	4,857,751	40,601,253	11,519,763,907	1.62	74.87	2.12	35.25

Table 4. 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

	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
Sertraline											
2000	22,128	22,128	86,250	3,017,865	3,024,921	7,295,130	1,222,483,968	3.03	136.38	3.90	34.99
2001	43,495	43,495	172,267	5,965,534	5,996,986	7,879,470	2,398,850,031	5.52	137.15	3.96	34.63
2002	40,863	40,863	161,284	5,625,781	5,645,371	7,868,671	2,384,636,120	5.19	137.67	3.95	34.88
2003	38,709	38,709	144,334	5,180,871	5,193,517	7,749,032	2,347,139,257	5.00	133.84	3.73	35.90
2004	35,767	35,767	129,456	4,611,786	4,612,517	8,122,391	2,373,789,269	4.40	128.94	3.62	35.62
2005	26,080	26,080	83,519	3,075,106	3,065,704	8,176,378	2,433,089,319	3.19	117.91	3.20	36.82
2006	58,321	58,321	232,730	8,707,262	8,686,088	18,244,959	4,041,639,241	3.20	149.30	3.99	37.41
2007	94,224	94,224	357,166	13,060,517	13,062,008	21,729,335	5,713,785,055	4.34	138.61	3.79	36.57
2008	174,817	174,817	616,461	22,057,910	22,031,450	41,694,377	9,464,109,289	4.19	126.18	3.53	35.78
2009	243,391	243,391	831,984	29,574,505	29,504,973	43,553,700	12,181,246,044	5.59	121.51	3.42	35.55
2010	230,596	230,596	738,611	26,131,940	26,053,995	41,601,177	11,696,604,103	5.54	113.32	3.20	35.38
2011	231,300	231,300	528,134	18,389,047	18,170,030	40,439,243	11,481,884,694	5.72	79.50	2.28	34.82
Venlafaxine											
2000	6,605	6,605	27,765	1,005,764	1,005,756	7,295,130	1,222,483,968	0.91	152.27	4.20	36.22
2001	14,736	14,736	61,306	2,231,469	2,229,606	7,886,023	2,400,095,503	1.87	151.43	4.16	36.40
2002	19,919	19,919	81,608	2,962,678	2,962,119	7,889,601	2,389,309,730	2.52	148.74	4.10	36.30
2003	22,028	22,028	86,217	3,304,230	3,297,810	7,779,406	2,354,417,635	2.83	150.00	3.91	38.32
2004	19,636	19,636	75,119	2,796,931	2,786,890	8,159,429	2,382,803,784	2.41	142.44	3.83	37.23
2005	13,371	13,371	45,386	1,859,661	1,846,006	8,217,897	2,443,605,971	1.63	139.08	3.39	40.97
2006	25,633	25,633	108,681	4,172,753	4,144,544	18,285,589	4,052,119,788	1.40	162.79	4.24	38.39
2007	37,300	37,300	162,004	5,809,361	5,810,255	21,779,206	5,726,503,546	1.71	155.75	4.34	35.86
2008	56,413	56,413	226,006	7,919,010	7,913,015	41,769,404	9,482,817,735	1.35	140.38	4.01	35.04
2009	57,540	57,540	209,963	7,394,307	7,364,270	43,674,811	12,210,712,400	1.32	128.51	3.65	35.22
2010	53,583	53,583	181,169	6,291,438	6,260,597	41,788,141	11,742,082,889	1.28	117.41	3.38	34.73
2011	56,878	56,878	130,299	4,451,366	4,391,821	40,680,379	11,541,978,105	1.40	78.26	2.29	34.16

Table 4. 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

	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
Vilazodone											
2000	0	0	0	0	0	7,295,130	1,222,483,968	0.00	---	---	---
2001	0	0	0	0	0	7,889,226	2,400,741,553	0.00	---	---	---
2002	0	0	0	0	0	7,900,719	2,391,908,653	0.00	---	---	---
2003	0	0	0	0	0	7,799,828	2,359,295,682	0.00	---	---	---
2004	0	0	0	0	0	8,191,046	2,390,513,438	0.00	---	---	---
2005	0	0	0	0	0	8,257,637	2,453,629,602	0.00	---	---	---
2006	0	0	0	0	0	18,324,956	4,062,471,075	0.00	---	---	---
2007	0	0	0	0	0	21,826,104	5,738,924,200	0.00	---	---	---
2008	0	0	0	0	0	41,830,114	9,498,682,812	0.00	---	---	---
2009	0	0	0	0	0	43,753,769	12,230,800,309	0.00	---	---	---
2010	0	0	0	0	0	41,881,903	11,766,674,357	0.00	---	---	---
2011	3,194	3,194	5,003	160,415	157,061	40,786,742	11,570,378,310	0.08	50.22	1.57	32.06

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

Data Partner ID	Start Date	End Date
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 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	All listed SSRI antidepressants	183	Sing	10	None
2	Desvenlafaxine	All listed SSRI antidepressants	183	Sing	10	None
3	Duloxetine	All listed SSRI antidepressants	183	Sing	10	None
4	Escitalopram	All listed SSRI antidepressants	183	Sing	10	None
5	Fluoxetine	All listed SSRI antidepressants	183	Sing	10	None
6	Paroxetine	All listed SSRI antidepressants	183	Sing	10	None
7	Sertraline	All listed SSRI antidepressants	183	Sing	10	None
8	Venlafaxine	All listed SSRI antidepressants	183	Sing	10	None
9	Vilazodone	All listed SSRI antidepressants	183	Sing	10	None

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